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How Scientist/Founders Lead Successful Biopharmaceutical Organizations: A Study of Three Companies

Lynn Johnson Langer
Antioch University - PhD Program in Leadership and Change

HOW SCIENTIST/FOUNDERS LEAD SUCCESSFUL BIOPHARMACEUTICAL ORGANIZATIONS: A STUDY OF THREE COMPANIES

Lynn Johnson Langer

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Approved by:

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Alan E. Guskin, Ph.D., Chair date

_____

Jon Wergin, Ph.D., Committee Member date

_____

Mitch Kusy, Ph.D., Committee Member date

_____

Alice Sapienza, DBA, External Reader date

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Abstract

The purpose of this study was to determine how the leadership of scientist/founders of biopharmaceutical companies affects the success of their organization. Over half of all biotechnology firms are founded by scientists, yet for every start-up biotech firm that succeeds, 15-20 fail and eight out of 10 drugs fail in clinical trials (Federal Reserve Bank of Dallas, 2007; Stanford Graduate School of Business, n.d.; Zhang & Patel, 2005). To bring a biopharmaceutical product from the research bench to the consumer costs more than $800 million (Tufts, 2007). This dissertation research explored the leadership practices of three successful scientist/founders and how their practices form the organizational context that leads to success. Based on the results of this study, there are a number of important factors that lead to success. The most important factor is that the leader must be adaptable and able to lead effectively in a highly dynamic environment. The leader needs to consistently articulate his or her vision throughout the organization. The leader needs to be a strategic decision-maker and be flexible enough to allow the strategic vision to adjust to the culture and the environment. The leader needs to be able to communicate effectively and create an organization where communication flows efficiently at all levels. The leader needs to recognize that clear cultural differences exist between functional groups. The leader must not give in to the common temptation among both scientists and business people to downplay the importance of these differences. Finally, organizational leaders need to empower their employees at all levels to make strategic decisions; but at the same time, the leader needs to know which decisions must be retained as his or her sole responsibility. The paradoxical nature of leading biopharmaceutical organizations in the 21st century requires leaders who are able to adapt their style and create learning organizations. The electronic version of this dissertation is at OhioLink ETD Center, www.ohiolink.edu/etd.

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Chapter I: Introduction

Overview

Biotechnology is a relatively young industry that has evolved rapidly since its commercial beginnings in the early 1970s. Since then, it has developed into a multibillion dollar industry with many successful products that have contributed to society with new biopharmaceuticals, food, and energy products and processes. Biotechnology is the use of genetically modified organisms to make products or solve problems. The industry is generally considered to have started with the first use of recombinant DNA techniques to make proteins, pioneered by geneticist Stanley Cohen, and biochemist Herbert Boyer, in the early 1970s. By 1976, Boyer, along with venture capitalist, Robert Swanson, founded Genentech, the first biotechnology organization. Genentech was created on the idea that genes could be spliced into bacteria that would then produce therapeutic proteins under highly controlled conditions. Genentech, working with Eli Lilly and Company, received the first United States Food and Drug Administration (USFDA) approval for a biotech therapy for recombinant human insulin in 1983. Since that time, biotechnology has produced "254 drugs approved for 392 indications, including treatments for cancer, diabetes, HIV/AIDS and autoimmune diseases. There are now more than 400 biotech drug products and vaccines currently in clinical trials targeting more than 200 diseases" (Biotechnology Industry Organization, 2007).

By early 2006, there were 1,415 biotechnology companies in the United States with revenues over $51 billion dollars. Biotechnology is the most research-intensive industry in the world; the U.S. biotech industry spent $19.8 billion on research and development (R&D) in 2005 alone (Biotechnology Industry Organization, 2007). Although biotechnology R&D has provided numerous benefits to society, many promising discoveries have not reached consumers because

of the difficulties involved in bringing new technologies to market. The high costs and resources required in early-stage research, discovery, and development of new biotechnology ideas can be prohibitive for all but the most promising projects. The Tufts Center for Drug Development estimates that it costs more than $800 million to bring a biopharmaceutical product from the research bench to the consumer (Tufts, 2007). This number includes the amortized costs of multiple failures and hundreds of millions in marketing costs.

The biotechnology industry is highly dynamic, and improvements and changes in research methods occur frequently. New technologies used in drug discovery, for example, may completely change how scientists conduct their investigations. These new discoveries must be assessed and put through the development cycle as quickly as possible. Even so, it may take ten years or more for new discoveries to reach consumers. Because this is such an expensive endeavor, many young, small companies depend on venture capital to survive. “Biotechnology attracted more than $20 billion in financing in 2005 and has raised more than $100 billion since 2000” (Biotechnology Industry Organization, 2007). As biotechnology firms mature, a financing strategy many biotech firms use is to partner with other biotech companies and with larger pharmaceutical firms. There were 354 agreements signed between biotech firms and 564 agreements signed with biotech companies and pharmaceutical firms in 2005 (Biotechnology Industry Organization, 2007).

Not all biotech firms are biopharmaceutical. The industry is divided into five major segments, biopharmaceutical, bioagricultural, bioremediation, diagnostics, and suppliers. However, the most potentially lucrative segment is biopharmaceutical. Because approximately 15 percent of the United States’ gross domestic product is spent on healthcare and 10 percent of healthcare is spent on prescription drugs, a blockbuster drug can represent significant revenue

and profit (Zhang & Patel, 2005). Henry Miller, MD., from Stanford, estimates that 13% of drug expenditures in the United States are biopharmaceuticals (Miller, 2007). A single blockbuster drug is expected to generate more than $1 billion in revenues for the owner (Chan, 2003). However, the drug approval process is a major entry barrier to the biopharmaceutical industry because it is so time and labor intensive and because the USFDA heavily regulates any drugs sold in the US. A recent report by the business intelligence firm, Cutting Edge Information, estimates that the cost per patient of running Phase 3 clinical studies of new pharmaceuticals exceeds $26,000, Phase 2 trials average just over $19,300 per patient, and Phase 1 trials, are estimated at $15,700 per patient (Life Sciences World, 2006).

The Drug Development Process

In 1906 Congress passed the Food and Drug Act, which is the foundation of food and drug law and, in 1938, passed the Food and Drug Cosmetic Act, which requires companies to prove the safety of new drugs before putting them on the market. The USFDA's Center for Drug Evaluation and Research (CDER) is responsible for ensuring that drugs are safe and effective. It takes approximately 12 years for a new drug to go from the research laboratory to the consumer (Wierenga & Eaton, 2007). "Only five in 5,000 compounds that enter preclinical testing make it to human testing. One of these five tested in people is approved" (Wierenga, 2007).

Preclinical Phase

Before a new drug can be tested in human beings, the sponsoring company or organization must demonstrate that the drug is reasonably safe by first testing the compound in animals. This research and development may take anywhere from three to six years. Testing is done to make sure the drug is not toxic and to determine how fast the drug and its metabolites are cleared from the body. The USFDA requires the company to give a pharmacological profile of

the drug, its toxicity in at least two species of animals (one rodent and one non-rodent) and short-term toxicity studies ranging from 2 weeks to 3 months (USFDA, 2007). The purpose of preclinical studies is to show that it is reasonably safe to proceed with human trials of the drug.

Clinical Studies

When preclinical testing is complete, the company submits a new drug application (NDA) to the USFDA. Studies in human subjects may only begin after the USFDA and an institutional review board (IRB) have reviewed and approved the data. The IRB is composed of scientists and non-scientists from the research institutions and hospitals that will oversee the clinical research. The company or drug sponsor must submit detailed information on manufacturing, drug data, and any test results from trials in humans and non-humans. “Human testing may have been performed in previous clinical testing or marketing of the drug in the United States or another country whose population is relevant to the U.S. population” (USFDA, 2007). Once clinical trials begin, “the drug is administered to a small number of humans and evaluated for safety and efficacy in treating, preventing or diagnosing a specific disease or condition” (USFDA, 2007). The overarching immediate concern of the USFDA is the safety of the human subjects in the clinical trials.

Phase 1 clinical trials. Phase 1 studies include the initial introduction of the new drug into humans. There are generally 20 to 80 subjects in the study. Subjects may be patients but typically they are healthy volunteers. “These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness” (USFDA, 2007). Phase 1 clinical trials usually take from six to twelve months to complete.

Phase 2 clinical trials. Phase 2 clinical trials are the preliminary studies to show effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are typically conducted in several hundred people and may take from six to twelve months to complete.

Phase 3 clinical trials. Only after preliminary evidence from the Phase 2 trials suggests that the drug is safe and may be efficacious do Phase 3 studies begin; these studies are intended to give more data to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies provide a basis for extrapolating the results to the general population and usually include several hundred to several thousand people. Phase III trials typically last from one to four years (USFDA, 2007).

Economics of the Biopharmaceutical Industry

The biopharmaceutical industry is obviously an extremely high-risk segment because of the extraordinary time and expense involved in getting a new drug approved. The potential revenue of more than $1 billions for a blockbuster drug draws many venture capitalists to the industry. It is the science, though, that makes the industry possible. Most biotech firms are started by biomedical scientists. In fact, “academic entrepreneurs account for 43.1 percent of biotech founders, far greater than any other industry” (Zhang & Patel, 2005, p. 58). Most biotech firms are clustered around either major research universities or institutes. Examples include Genentech, near the University of California, in San Francisco, Biogen-Idec, close to its founders from Harvard and MIT in Cambridge, Massachusetts, and Amgen, close to its founders from the University of California, Los Angeles. Other companies are clustered around major research centers such as the National Institutes of Health, in Bethesda, Maryland, including Human

Genome Sciences and MedImmune. For every start-up biotech firm that succeeds, 15-20 fail and eight out of 10 drugs fail in clinical trials (Federal Reserve Bank of Dallas, 2007; Stanford, Graduate School of Business, n.d.).

Zhang & Patel (2005) analyzed data they obtained from VentureOne, a venture capital research firm. The data covered venture capital deals from 1992 through 2001 for biopharmaceutical firms. Zhang & Patel's research looked at 665 total companies, with 79 percent founded from 1990 on. Of these firms, 70 percent were still developing or testing their products. They found that within the entire biotech industry, only ten of 526 firms founded since 1990 were profitable. Therefore, the venture capital money is not spent on production, but R&D.

> Our findings suggest that although venture capital investment is a key ingredient of the biotech industry, it alone cannot create a strong biotech economy. And thus, simply pouring money into the industry is not likely to make it grow significantly faster. Other measures, especially strong support to biotech research in academic institutions and streamlined transfer of technology to the industry, are necessary (Zhang & Patel, 2007, p. 53).

However, support of research and technology transfer does not adequately address the requirements and conditions for success within biopharmaceutical firms.

Zhang & Patel (2005) also looked at 351 biotech firms that had founder information and determined that 626 entrepreneurs were involved in starting firms. They examined the career paths of the founders and discovered that 43.1 percent of biotech firm founders were university-based professors or researchers; another 2.6 percent undertook research at nonprofit institutes. By adding new Ph.D. students to these two groups, we found that 292 (or 46.7%) of the 626 entrepreneurs had engaged in nonprofit research. These 292 individuals founded or co-founded 203 (or 58.2%) of the 351 biotech firms for which founder information is available. Given that 92.6 percent of those firms with founder information were started in or after 1990, we argue that

the important role of academic researchers in founding biotech firms continued through the 1990s (p. 57).

Zhang & Patel (2005) argue that strong research has and will continue to be a critical component of the biotechnology industry along with venture capital. Other conditions must certainly exist for a biopharmaceutical company to be successful and ultimately make a profit.

Given that the majority of biopharmaceutical firms are started by research or academic scientists, the success of these firms is dependent on either the founder/scientist intuitively knowing how to successfully run an organization or business talent being brought in. Pisano (2006) defines success in the biotechnology industry as, "how effectively an organization or industry uses the capital it raises, and more specifically, how well it creates true value from its activities. Ultimately, value creation and capture are what matters" (p. 162). Pisano argues that existing approaches to business and organizations are not satisfactory to biotechnology. "Organizational and institutional innovations are needed in order to unlock the potential of biotechnology" (p. 202).

Given that only about five percent of biopharmaceutical organizations succeed and most organizations are founded by scientists, questions arise about what conditions in biopharmaceutical organizations are necessary for success (Zhang & Patel, 2005). There are some highly successful biopharmaceutical organizations with scientist founders. Notable examples include Genentech, Amgen and Genzyme. What are the leaders of these organizations doing right given that so many fail?

Moving Science Out of the Laboratory

In an earlier, preliminary study, I reviewed almost 300 research studies that yielded 13 articles related to how best to move ideas from the laboratory. Additionally, I interviewed nine

leaders from the biotechnology industry: Five were scientists holding doctorates of philosophy (PhD), one held a master's of science (MS) in biotechnology and a juris doctorate, two held an MS in chemistry, and one was a nonscientist with a business background. Each respondent was asked, "What do scientists do to successfully move ideas from the laboratory and engage business leaders to take action?" Results from the conversations indicated a diversity of factors; however, the consistent, emergent theme was the social interaction that permitted effective communication between both scientists and business professionals. This factor appears to be critical in moving ideas from the laboratory.

Other themes also emerged in the literature and through the conversations, including: networking, culture, organizational processes, and leadership. These themes have different levels of influence on the process. Many scholars and practitioners agree that communication is the key element required for moving ideas out of the laboratory. However, several factors influence the organization's and the individual's ability to communicate effectively. These factors include the ability and encouragement to network in a culture conducive to open communication and having formal organizational processes in place to permits the flow of ideas out of the laboratory. Finally, these factors are directly affected by the organization's leadership and its ability to set a tone that allows and encourages open communication.

Clearly, the nation's health is affected by the success of biotechnology and particularly the biopharmaceutical industry. Very little research has been done on effective methods for helping scientists succeed when they start a new biopharmaceutical company. Some of the research that has been done indicates that opportunities for communication between business people and scientists are important (Allen, 1984; Argote & Ingram, 2000; Hirst & Mann, 2004; Kivimaki, Lansisalmi, Elovainio, Heikkila, Lindstrom, Harisalo, Sipila, & Puolimatka, 2000;

Nonaka, 1995; Rogers, 2003; Yin and Gwaltney, 1981). Other studies have examined leadership in R&D organizations (Elkins & Keller, 2003; Hirst & Mann, 2004; Sapienza, 2005; Shim & Lee, 2001). Tidd, Bessant, & Pavitt (2005) studied 94 biotechnology start-up businesses and found that three factors were associated with success: location within a significant concentration of similar firms, quality of scientific staff (measured by citations), and the commercial experience of the founder.

Communication is a critical component in moving ideas from the laboratory to engage business leaders to take action. However, to understand what happens in organizations that are moving ideas successfully, one must consider not only the scientists but also the collective processes that include communication, networking, leadership, and organizational culture. Yet, the typical organizational culture within biotechnology companies tends to be more oriented toward individual research and scientific discovery, and less on human interactions. This characteristic is deeply embedded in scientists and as one scientist/leader with whom I spoke stated: “scientists who move into business or try to have their science translated into business think they are selling themselves to the devil.”

Conclusion

Because many biopharmaceutical organizations are founded and run by scientists, this dissertation focuses on the leadership practices of three scientist/founders and how these practices form the organizational context that leads to success. I used a multi-case method because according to Yin (2003b) a case study is the right choice of inquiry when the researcher wants to know how and why events occur, and has little or no control of the events. I interviewed the scientist/founders, their senior executives and three outside expert consultants using broad, open-ended questions and NVivo software to help analyze the data. I also had a research team of

graduate students review my coding and analysis to confirm my findings. My research and data analysis allowed me to deconstruct and analyze themes that emerge.

My personal experience in the field began with my work as a microbiologist at the National Institutes of Health in 1974. I later moved from the laboratory into the private business sector, where I worked in sales and marketing until I started a biotechnology consulting firm in 1990. I continued as the leader of that organization until 2001, when I began working as a full-time faculty administrator at The Johns Hopkins University in the graduate programs of the Krieger School of Arts and Sciences, Advanced Biotechnology Studies. My personal observations regarding the cultural differences between scientists and business administrators have led me to inquire how these differences occur. My position in the biotechnology industry as both an academic and an administrator gives me a unique perspective on the situation. My office is located in what Time Magazine calls “DNA Alley,” an area outside of Washington, D.C. in which there are more than 200 biotechnology firms within a ten mile area (Buia, 2000). I am also within walking distance of the Food and Drug Administration and within ten miles of the National Institutes of Health.

I work and interact with biotechnology professionals in federal, academic, private, and public organizations. My relationship to the biotechnology industry provides me access to industry executives, and has increased my interest in the overall success of biotechnology. My earlier research into the interactions between biopharmaceutical leader/managers and their organizations’ scientists has led me to want to investigate more deeply the conditions for success in biopharmaceutical firms. It may be the future products from these companies that save the life of someone I love. If this research can support more efficient therapeutic development, it may

help bring discoveries to patients who otherwise would not receive the benefit of a new drug or diagnostic.

In the next chapter, I build a framework for success through an in-depth analysis of the research literature as it relates to scientists as leaders of biopharmaceutical organizations. Most of the literature tends to involve quantitative research, and chapter two, Literature Review describes a need for a more qualitative approach to better understand the dynamics within a successful biopharmaceutical organization. The chapter begins with a brief review of the strategies leaders must use to lead change and will continue with a closer examination of leading R&D scientists and what the scientists themselves could do to promote success within the biopharmaceutical organization.

Chapter three, Methodology, describes the methodology I used to carry out the research. I describe the multi-case method of research that is to be implemented, the use of NVivo in my analysis, and I present the companies, leaders, and expert consultants I researched. I describe the interview template I used to interview the leaders. I also describe the archival data I collected regarding the leaders and their organizations.

Chapter Four describes my findings from the interviews with the scientist/founders, senior executives, and archival data I collected. The data is presented in three separate case studies and I include a section on findings from my interviews with the expert consultants.

Chapter Five presents an analysis of my findings, limitations of this research and suggestions for how scientist/founders can successfully lead biopharmaceutical organizations.

Chapter II: Literature Review

Introduction

Biopharmaceutical organizations, like other technology-driven organizations, are dynamic and undergo constant change, due to both internal and external forces. To be successful, organizations must adapt to the environment, and leaders must understand how to lead in uncertain circumstances. Because of the long cycle time to commercialize new drug discoveries, leaders, and the organization itself, must regularly transform. Requirements for managerial and technical capabilities within an organization differ from one stage of drug development to the next. However, successfully moving the fruits of scientific discovery from the laboratory to commercialization requires a greater focus on leadership, organizational behavior and finance than on other functional or operational areas of the organization.

Financial strategies for commercializing technologies are well researched and reported on by large consulting firms such as Ernst and Young, McKinsey, PricewaterhouseCoopers and others. There is a need, however, to understand from the literature the leadership practices in successful biopharmaceutical organizations. A large body of literature exists on strategies for leading change in organizations. There is also literature available on how to lead research and development scientists. However, the organizational behavior and what scientists themselves must do to move ideas from the laboratory to engage business leaders to take action are not as well researched. Most biopharmaceutical organizations are in the early stages of the company's lifecycle. Lifecycles of organizations are also well-researched, but none of the current research specifically relates to the biopharmaceutical industry; although recent literature does mention the need for new organizational structures to meet the needs of the modern organizations (Greiner, 1998).

This chapter reviews the seminal leadership literature regarding practices and strategies for leading change, organization change literature, research regarding leading R&D scientists, and literature about what scientists need to do to successfully move ideas from the laboratory. The chapter will then review the popular literature regarding the drug development process and literature concerning success and failure in biopharmaceutical organizations. The chapter points out the need for additional research to specifically address the how scientist founders lead successful biopharmaceutical organizations.

General Leadership Practices and Strategies

To successfully negotiate critical organizational changes, leaders work within a framework of responsibilities. However, these responsibilities need to be balanced against individual and organizational needs to ensure changes are effectively implemented. I reviewed more than forty books and journals to determine the common themes of strategies leaders should use to implement change (see Table 1 in Appendix A). I chose to review the publications because they offer specific strategies for the leader, as opposed to studies of leadership traits or personalities. Interestingly, most scholars mention vision as a crucial component of leading any organizational change (Bennis & Nanus, 1997; Brown, 1995; Covey, 1996; Dess & Picken, 2005; Drath, 2001; Farkas & De Backer, 1996; Gardner, 1995; Geller, 2002; Gill, 2003; Greenleaf, 1991; Greiner, 1998; Heifetz, 1994; Hemp & Stewart, 2004; Kanter, 2004; Kellerman, 2004; Kotter, 1996, 1999; Kouzes & Posner, 2002; Miller, 2002; O'Toole, 1995; Rooke & Torbert, 2005; Ruvolo & Bullis, 2003; Senge, 1990; Skipton, 2003; Wheatley, 1999). Most also mention that the organization needs to become a learning organization and be able to adapt to new problems and challenges (Bennis & Nanus, 1997; Brown, 1995; Dess & Picken, 2005; Drath, 2001; Greiner, 1998; Handy, 1995; Heifetz, 1994; Heifetz & Laurie, 2001;

Kellerman, 2004; Kotter, 1996; Kouzes & Posner, 2002; McGregor, 1957; Miller, 2002; Pascale & Sternin, 2005; Priestland & Hanig, 2005; Ruvolo & Bullis, 2003; Senge, 1990; Vaill, 1996; Wheatley, 1999). Another frequently mentioned strategy mentioned in the literature is the importance of good communication and active listening by the leader. Creating a sense of urgency or a disorienting dilemma was also cited as important in change leadership (Kotter, 1996; Mezirow, 1991). Some scholars mention that the leader needs to embody his, or her, own story, view the organization as an entire system and, recognize that what affects one area of an organization can also impact others (Bennis & Nanus, 1997; Gardner, 1995; Senge, 1990). The necessity of a culture that is sensitive to the needs of the members in the organization and creates a holding environment for employees is also ranked as important (Heifetz, 1994; Senge, 1990).

Vision and Values

More than half of the publications I reviewed mention that the primary responsibility of a leader is to create and articulate a guiding set of principles. These principles may be stated either in the form of vision for the overall organization or as a set of guiding values (Bennis & Nanus, 1997; Brown, 1995; Covey, 1996; Dess & Picken, 2005; Drath, 2001; Farkas & De Backer, 1996; Gardner, 1995; Geller, 2002; Gill, 2003; Greenleaf, 1991; Greiner, 1998; Heifetz, 1994; Hemp & Stewart, 2004; Kanter, 2004; Kellerman, 2004; Kotter, 1996, 1999; Kouzes & Posner, 2002; Miller, 2002; O'Toole, 1995; Rooke & Torbert, 2005; Ruvolo & Bullis, 2003; Senge, 1990; Skipton, 2003; Wheatley, 1999). A vision inspires and helps create confidence in the followers so that they themselves may become leaders. “The visions…seemed to bring about a confidence on the part of the employees, a confidence that instilled in them a belief that they were capable of performing the necessary acts” (Bennis & Nanus, p. 30). Embodying a mission and a clearly articulated vision are a means for expressing values. Covey (1996) argues that

future leaders must create organizations based on values. A main role of leadership means "ensuring that your organizational structure, systems, and operational processes all contribute to achieving your mission and vision of meeting the needs of customers and other stakeholders" (p. 152).

Trust must be earned by the leader and one way to do so is to embody the vision that is espoused. When leaders actively live through their actions and words the vision for the company, others will follow. "In the end, trust, integrity, and positioning are all different faces of a common property of leadership—the ability to integrate those who must act with that which must be done so that it all comes together as a single organism in harmony with itself and its niche in the environment" (Bennis & Nanus, 1997, p. 186). Howard Gardner (1995) offers a cognitive theory of leadership through narrative and communication of a story. "The ultimate impact of the leader depends most significantly on the particular story that he or she relates or embodies, and the receptions to that story on the part of audiences (or collaborators or followers)" (p. 14).

If the individual wishes to lead change it is simpler with a small group of cohesive followers of like minds. Generally, these individuals have a more sophisticated understanding of the need for change. However, as the domain increases in size, the group is less cohesive and the narrative embodied by the leader must be aimed at the unschooled mind, or as Gardner (1995) says, the mind of the five-year-old. "But when a leader wants to promulgate a story that is more sophisticated—that calls, for example, for a broader definition of one's social group—she can succeed only if she educates the unschooled minds of the audience" (p. 29).

There needs to be a sense of urgency and a guiding coalition in bringing about change. A vision is necessary to "help direct, align, and inspire actions on the part of large numbers of people" (Kotter, 1996, p. 7). The vision should be brief and clear enough to be articulated in five

minutes or less. The followers need to be able to understand and be able to articulate the message. If it is not clear or concise, the followers may not fully comprehend the vision and will not be able to maintain a true sense of urgency and need.

Learning Organizations and Adapting to Challenges

Many authors also argue the importance of creating a learning organization that is able to creatively solve problems that have not been faced before. (Bennis & Nanus, 1997; Brown, 1995; Dess & Picken, 2005; Drath, 2001; Greiner, 1998; Handy, 1995; Heifetz, 1994; Heifetz & Laurie, 2001; Kellerman, 2004; Kouzes & Posner, 2002; McGregor, 1957; Miller, 2002; Pascale & Sternin, 2005; Priestland & Hanig, 2005; Ruvolo & Bullis, 2003; Senge, 1990; Vaill, 1996; Wheatley, 1999). This is especially important in technology industries where innovation, discovery and competition constantly pressure participants to react to, and predict change. Peter Senge (1990) offers an excellent description of a learning organization, as one "where people continually expand their capacity to create the results they truly desire, where new and expansive patterns of thinking are nurtured, where collective aspiration is set free, and where people are continually learning how to learn together" (p. 3). To create a learning organization, Senge writes that leaders must embrace five disciplines, including a shared vision, mental models, team learning, personal mastery, and systems thinking. Although these disciplines may be learned individually, to truly become a learning organization, the organization must be viewed as an entire system, similar to a symphony that is not just the musical notes, but the musicians, the instruments, the conductor, and composer. Senge points out that "learning organizations demand a new type of leadership," with the leader as learner as opposed to the traditional view of leader as hero (p. 337).

In his book, *Learning As A Way Of Being*, Peter Vaill (1996) argues that leaders need to be engaged in a continual learning process he refers to as "leaderly learning…. Managerial leadership is not learned; managerial leadership is learning" (p. 126). He states that leaderly learning must be an ongoing part of a manager's workday and that the "meaning of the managerial leader's responsibilities is altered. His or her relationships to colleagues are altered, especially team relationships" (p. 127). This relationship to colleagues and to the concept of learning itself is defined by Vaill as requiring seven types of learning. These include self-directed learning, creative learning expressive learning, feeling learning, online learning, continual learning, and reflexive learning. Self-directed learning refers to the fact that situations that happen to an individual at work may be totally novel. There may be no course one may take to learn to deal with a particular situation. Therefore, the learner must self-direct the education required to deal with the situation. "Creative learning is exploration; to be an explorer is literally not to know exactly where you are going…learning in permanent white water has to be strongly creative, exploratory, and inventive" (p. 45). Expressive learning means learning as we are actually doing the activity. The example Vaill uses is being thrown in the water and having to learn to swim. Feeling learning is "trying to learn in an environment of constant unpredictable change can that lead learners to feel that they are not getting anywhere—or indeed are going backward, becoming progressively more incompetent…It has to be learning about *meanings*—how meanings are formed, how they are challenged or lost, how they can be sustained and revitalized" (p.46). Vaill refers to online learning as "deinstitutionalized learning" (p. 46).

Vaill (1996) argues that because the previous six types of learning are so difficult, learning about learning and how to learn becomes crucial. The seventh type of learning is reflexive learning and it means becoming more aware of our individual way of learning and how

to continually enhance our learning. Thus, leaderly learners must possess enough self-knowledge that they are able to put themselves in situations where they have the opportunity to continually learn and grow. They may even jump in the deep-end to learn to swim.

Heifetz (1994) also discusses the importance of vision and values in leadership, but additionally “examines the usefulness of viewing leadership in terms of adaptive work. Adaptive work consists of learning required to address conflicts in the values people hold, or to diminish the gap between the values people stand for and the reality they face. Adaptive work requires a change in values, beliefs, or behavior. The exposure and orchestration of conflict--internal contradictions-- within individuals and constituencies provides the leverage for mobilizing people to learn new ways” (p. 22).

Bennis and Nanus (1997) interviewed 90 leaders, “sixty [were] successful CEOs, all corporate presidents or chairmen of the boards, and thirty with outstanding leaders from the public section” and use story telling and narrative to fully describe the strategies they learned from them (p. 20). Interestingly, all 90 leaders interviewed indicated a need for continual learning. “Leaders have discovered not just how to learn but how to learn *in an organizational context*" (p. 188). Learning is critical for leading change because new problems will be faced for which there is no obvious solution. "Innovative learning is more difficult [than maintenance learning] because it focuses on preparing organizations for action in new situations, requiring the anticipation of environments that have not yet appeared" (p. 194.)

In addition to ‘learning’, problem-solving, and ongoing learning aimed at developing new ways to solve problems was indicated by many researchers as a critical component of effective leadership. Drath (2001) concurs with Heifetz and Vaill in his book, *The Deep Blue Sea*. He notes that there are some problems for which there are no known solutions. The group or

individual must create the solution or learn a new way to solve the problem. According to Drath, for the problem to be solved, the group must share meaning of what the problem is. Drath states that the ability to face adaptive problems and find their solutions is crucial to the existence and success of the organization. To be dynamic and face rapid change requires a learning organization with clearly defined values and mission. Clear communication is necessary for problem-solving, and for organizations to be successful.

Communication

Communication is vital when leading change (Bennis & Nanus, 1997; Brown, 1995; Dess & Picken, 2005; Drath, 2001; Farkas & De Backer, 1996; Foster, 2004; Gardner, 1995; Geller, 2002; Greiner, 1998; Handy, 1995; Heifetz, 1994; Heifetz & Laurie, 2001; Hesse, 1956; Kanter, 2004; Kotter, 1996, 1999; Kouzes & Posner, 2002; Miller, 2002; Priestland & Hanig, 2005; Rooke & Torbert, 2005; Ruvolo & Bullis, 2003; Skipton, 2003; Vaill, 1996; Wheatley, 1999). The vision of what the change will bring must be articulated in every way possible and that vision must be demonstrated through the behavior of the leader. The leader should use “every vehicle possible to constantly communicate the new vision and strategies…and the guiding coalition must model the behavior expected of the employees” (Kotter, 1996, p. 21). Once the vision is created, a leader’s primary job is to communicate the vision. "Leaders are only as powerful as the ideas they can communicate" (Bennis & Nanus, 1997, p. 107). As organizations grow, communication needs to be enhanced and processes need to be established to ensure that all levels of the organization are involved in a give and take of information. Enhanced communication needs to be system wide and the organization needs to be viewed in its entirety.

Positive Systems Culture

Leaders who view the entire organization as a system and strive to create a culture of positive interaction throughout the organization are more likely to be successful. The importance of field theory, systems organizations, a positive culture, and a holding environment were mentioned by several authors (Bennis & Nanus, 1997; Foster, 2004; Gardner, 1995; Heifetz, 1994; Heifetz & Laurie, 2001; Herrigel, 1999; Kanter, 2004; Kouzes & Posner, 2002; O'Toole, 1995; Rooke & Torbert, 2005; Senge, 1990; and Wheatley, 1999. Leaders must recognize that individual actions affect the organization as a whole. An environment that is open and conducive to sharing ideas leads to the alignment of goals between employees and the organization (Brown, 1995; Covey, 1996; Dess & Picken, 2005; Geller, 2002; Gill, 2003; Kouzes & Posner, 2002; McGregor, 1957; Rausch, Halfhill, Sherman, & Washbush, 2001; Skipton, 2003. According to Brown (1995), goal integration must occur before true change can happen. Brown states that managers must understand the individual needs of the subordinate and help to align those needs with the goals of the company. When the company lacks a visionary and articulate leader, then even senior management may not fully understand the vision for the company and may not be able to align their individual goals, or the goals of their subordinates, with those of company. Goal integration requires followers to be actively involved in the success of the organization.

Follower's Responsibilities

For leaders to successfully lead change, followers must feel comfortable to actively engage in the process of change. The founder/leader needs to have helped create a culture conducive to being actively engaged in the change process. Many authors indicated that followers must be prepared to attempt to understand the changing organizational structure and needs. According to Greiner (1998), followers must be willing to accept changing responsibility

and new job requirements. McGregor (1957) stated that "the individual is encouraged to take a greater responsibility for planning and appraising his own contribution to organizational objectives; and the accompanying effects on egoistic and self-fulfillment needs are substantial" (p. 19). Kellerman (2004) describes the responsibilities of followers and how they can "strengthen their personal capacity to resist leaders who are ineffective or unethical" (p. 239). She first suggests followers empower themselves and to regularly remind themselves that they have power and control. She then suggests followers be skeptical, take a stand, and pay attention. When followers are working with others, Kellerman says followers should "…find allies…develop [their] own sources of information… take collective action…be a watchdog…and…hold leaders to account" (pp. 241-243). A culture conducive to new ideas is crucial to leading change. Followers can be a positive influence on the change when leaders have helped to create an environment accepting of new ideas and where some failure can be tolerated.

Small Wins

Change can be difficult and often overwhelming to managers as well as employees Small wins can help to encourage those involved with the change (Kanter, 2004; Kotter, 1996, 1999; Kouzes & Posner, 2002). Small wins can encourage a cycle of confidence-building that grows to other areas of the organization. As wins begin to proliferate, mistrust and non-cooperation begins to dissipate (Kanter, 2004). Teams experiencing small wins find that success encourages the teams to take more initiative, more risks, and to collaborate to a greater extent. Additionally, the leader should "experiment and take risks by constantly generating small wins and learning from mistakes" (Kouses & Posner, 2002, p. 22). Employees need to feel they are making progress and need to see successes. However, employees still need to feel a sense of urgency, or the

employees may feel that the short-term wins are sufficient. Complacency may then set in and true lasting change will not happen (Kotter, 1996, 1999).

The previous section of the chapter reviewed a broad range of leadership literature related to strategies and tactics that leaders might use to successfully lead organizations. Most leadership scholars agree on several points: Create a vision, establish a learning organization, and ensure good communication; take a systems view; and create an environment where followers are free and encouraged to accept responsibility. Leadership scholars point out that some individuals are born with good leadership traits, yet everyone, both leaders and followers, can learn to become *better* leaders (Bennis & Nanus, 1997; Heifetz, 1994; Senge, 1994; Vaill, 1996). Taking responsibility, breaking boundaries and barriers, communicating clearly (and this includes active listening), believing the vision, embodying the story, motivating, empowering, and creating a sense of urgency are all elements of personal and organizational strategies required to lead change. However, change requires more than a good leader. The strategies employed by the leader must be appropriate to the organization and its phase in the life cycle of the organization.

Organization Phase

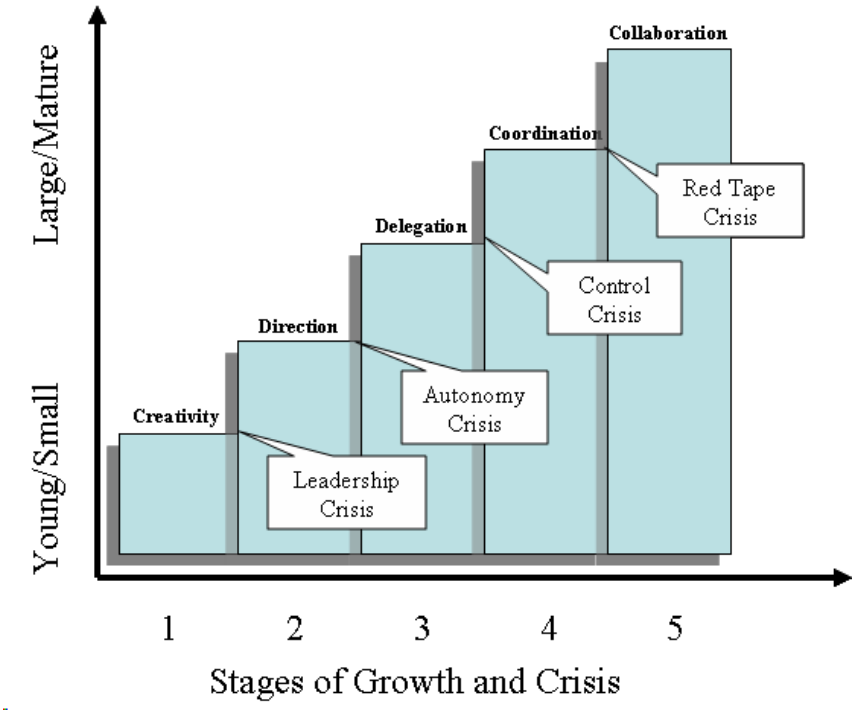
Leadership strategies alone are insufficient to successfully lead biopharmaceutical organizations. Greiner (1998), Handy (1995), and Skipton (2003) discuss the importance of the organizational phase to the leader and leadership strategy. In the 21st century new types of organizations are required. Because of the rapidly accelerating rate of change within our economic systems, organizations will need to be increasingly more fluid and adaptable, as organizations have evolved from the Industrial and Modern Age to Postmodern organizations. Greiner (1972, 1998) describes the leadership and followership requirements of the organization as it proceeds through its life cycle. It should be noted that biopharmaceutical organizations

progress somewhat more slowly through an organization life cycle, partly because of the long time required to develop new drugs.

Greiner's (1998) Phase 1 of the organization life cycle requires an entrepreneurial leader who is charismatic and communicates frequently and informally. (Phase 1 is similar to the startup phase of a new biopharmaceutical organization.) Greiner's Phase 2 describes the more mature organization that requires leaders who are more directive and able to put formal processes in place that better handle company functional areas such as finance and marketing. (Because biopharmaceutical companies have products in the pipeline, specific processes that adhere to USFDA standards and regulation must be in place. For some scientists, it is difficult to adjust to these highly structured requirements.) As the company continues to mature, into Phase 3, it requires the leader to delegate more responsibility and become more decentralized. "Much greater responsibility is given to the managers of plants and market territories" (p. 62). Communication from the senior executive to the lower levels in the hierarchy is now formal and infrequent. In Phase 4, a formal structure is required with more formal planning procedures. Product groups replace decentralized units. The final or most mature phase of the organization is Phase 5, where collaboration is required to overcome the red-tape of the now large bureaucracy. A matrix-style structure is implemented where cross-departmental groups are able to interact and solve problems.

Organizations generally pass from one stage of growth into another by what Greiner (1998) describes as crises (see Figure 2.1).

Figure 2.1 Greiner's Stages of Growth and Crisis



A crisis of leadership is what propels an organization into Phase 2, when the entrepreneurial leader is no longer able to single-handedly run the organization. Phase 3 is brought about by a crisis of autonomy. "Lower-level employees find themselves restricted by a cumbersome and centralized hierarchy. They have come to possess more direct knowledge about markets and machinery than do their leaders at the top; consequently, they feel torn between following procedures and taking initiative on their own" (Greiner, 1998, p. 60). This crisis is resolved by more delegation to lower-level managers. Particularly with lower-level scientists, many may feel frustrated as they may feel they know more about their duties and responsibilities than their doctoral-educated PhD scientist supervisors.

The third crisis occurs at the end of phase 3 when "top-management teams attempt to return to centralized management, which usually fails because of the organization's new vast

scope of operations. Those companies that move ahead find a new solution in the use of special coordination techniques" (Greiner, 1998, p. 62). The attempt to return to centralized management ultimately gives way to the crisis of red-tape. Managers become frustrated with direction from off-site senior management direction not in tune with local conditions. Both senior and lower-level managers are critical of the bureaucratic system.

Leaders must carefully analyze the stages of organizational development and be prepared, in advance, to put managers and systems into place before the organization devolves toward entropy. Followers must be prepared to understand the changing organizational structure and needs and be willing to accept changing responsibility and new job requirements. Leaders are responsible for educating their followers in this regard. Greiner (1998) argues that learning from the history of changing organizations, leaders and followers can be better prepared to grow with the company. Both leaders and employees can better determine whether they wish to continue with the changing organization or find a company in the organizational stage to which they are most happy and best-suited. (Successful biopharmaceutical organizations are able to successfully navigate the changes required at each stage.)

Handy (1995) describes four main types of organizations using Greek Gods as an analogy. A Zeus organization is defined as a group with one powerful leader. Those closest to the leader are the ones most trusted and who have conferred power. A Zeus organization is similar to Greiner's Phase 1 leader (Greiner, 1998). Apollo is the typical hierarchical situation where the organization is divided by functional areas and the workers are defined by their role in the area. This organization type is typified by the government bureaucracy or a government laboratory. Handy claims that in the Apollo organization, workers are the "servant of technology…and are hired to operate, service or often just watch increasingly sophisticated

equipment…and be in many senses its servants" (p. 191). This organizational structure is similar to Greiner's Phase 4 organization, or in the Coordination phase.

In an Athena organization, short-term project groups are assembled to solve problems and consist of whoever is needed from different functional areas. Lastly, the Dionysus organization is a group of independent individuals loosely joined by a common need, such as a group of lawyers sharing a suite with a shared office manager. University departments are often formed in the Dionysus style. According to Handy (1995) the university is a Dionysus organization: "The organization exists to help the individual achieve his purpose" (p. 24). The Athena organization is similar to Greiner's Phase 5, or Collaboration phase, and is often how biopharmaceutical companies begin.

Relatively few people are suited to employment at all stages of a company's development. Yet for leaders to be constantly growing a company from one phase to another is regarded in much the same way as promotions within American companies. Success is based on title, position, and salary. To be considered successful, scientists may be expected to leave the lab and manage people; a job responsibility in which they may have no training or support. "Organizations must respond continually to their environment, even if they do not themselves set out to change it" (Handy, 1995, p. 81). New organizations in the 21st century, according to Handy, are moving away from this paradigm to newer organizational structures that are more short-term and team-project oriented. Handy predicts that the factory or the office will "give way…to a more contractual, dispersed and federal organization. It will lead to more small businesses, particularly in the services and more self employment" (p. 7).

Leonard Skipton (2003) describes the evolution of leadership theory over the past 50 years, but also discusses what the postmodern organization must do to foster new types of

leaders. “The requirements for leadership change in contemporary organizations have changed significantly in the past several decades” (p. 3). Additionally, Skipton states that there must be “a clear line-of-sight between leadership training and participant goals and objectives must be demonstrated in order to motivate many participants effectively” (p. 11). Program developers must also “place a high priority on shaping the work environment that participants go back to so that (a) they have an opportunity to practice their new skills on real-world task and problems and get useful feedback and (b) the organization will support and reward them for not only taking the course, but also demonstrating the new capabilities on the job” (p. 11). Leadership programs “must incorporate personal organizational missions, strategic goals, cultural values and assumptions, and core challenges for the sponsoring organization in order to engage both the participant and the larger organization in the developmental process” (p. 12).

Are traditional leadership strategies sufficient to successfully lead biopharmaceutical organizations? The next section of this review will examine the literature specifically concerning “How to lead Research & Development (R&D) Scientists?”

Leading R&D Scientists

The unique challenges involved in leading scientists and engineers have been extensively researched during the past decade. More recently, scientists in the biotechnology industry have specifically been the focus of inquiry with regard to differences in leadership, and the effectiveness of leadership approaches. The biotechnology industry is relatively young and is experiencing rapid growth. Many of the discoveries in biotechnology have come from scientists and researchers in government and academic laboratories. Often, highly intelligent scientists leave the laboratory to join commercial organizations, or newly formed, non-profit product development partnerships (PDPs).

PDPs are new organizational structures whose mission is to develop and distribute drug products for under-served diseases. PDPs are funded by contributions from major foundations, such as the Bill and Melinda Gates Foundation, and governments and have been created to fill a gap left by traditional biopharmaceutical companies. Traditional for-profit companies often do not focus on diseases with small populations or diseases that mainly affect third-world countries because the profit margins are too low to justify the very large investments required for research and development for new drugs.

PDPs are often unique in that they can have a more traditional business focus and results-orientation that are not typical for non-profit organizations. This hybrid-type organization may well become a key player in the future of biopharmaceutical drug development, especially for major diseases such as HIV/AIDS, Tuberculosis and Malaria that ravage poor countries. This shift may become more common as the relatively large wealth that young, technology-oriented entrepreneurs with altruistic values have accumulated, such as Bill and Melinda Gates. Because the concept of the PDP has only recently been created, there is currently no scholarly literature on leadership and PDPs.

However, scientists who work in PDPs face the same difficulties as other scientists that may leave academia. These scientists may bring with them cultures and attitudes that are not effective in a highly goal-oriented environment, regardless of whether it is a for-profit, or otherwise. For biotechnology discoveries to ultimately reach the consumer, scientists must frequently shift from a purely research mentality to one of rapid development, production, and commercialization. This shift in perspective is a major issue as many biotechnology organizations are led by former researchers who lack business experience. The question

examined in the literature is, “What leadership practices enhance performance of scientists in R&D groups?”

I evaluated more than 250 articles and categorized them into four specific themes that relate to the research question. These include: Supervisory practice, performance, autonomy, and creativity. In addition to these categories, Mumford, Scott & Gaddis (2003) describes 37 specific propositions for leading scientists. These will be discussed at the end of this section. Researchers used several types of inquiry, including qualitative, quantitative, and mixed methods. The literature cited is chosen because it is a good representation of the themes discovered and because it represents a variety of relevant research methods.

Supervisory practice

Supervision of scientists varies by individual, but because scientists tend to be creative and prefer autonomy, leading scientists can be different than leading individuals in the general population. Supervisory practice may include both leaders and managers. Transformational or facilitative leaders can balance the negative effect of obstacles in the climate of R&D teams (Pirola-Merlo, Härtel, Mann, & Hirst, 2002). Transformational leadership is related to employee satisfaction in R&D teams, but transformational leadership is unrelated to creativity because it distracted people from activities at hand (Berson & Linton, 2005; Sosik, Kahai, & Avolio, 1999). The traditional leadership strategy of clearly defining goals may actually reduce intrinsic motivation in R&D scientists (Hennessey & Amabile, 1988a; Mullin & Sherman, 1993). Sapienza (2005) studied how scientists define effective leaders, and Cordero, Farris, & DiTomaso (2004) examined supervisory practice as it relates to performance and the work environment.

As scientists transition from individual contributor to team player, the skills required to perform also change. Scientists, whose leadership responsibilities require 25% or more of their time, practice leadership skills, as defined by Kouzes & Posner (2003), more frequently than those scientists who spend less than 25% of their time leading. These practices include inspiring a shared vision and encouraging the heart, by recognizing contributions and celebrating values. Scientists are more effective when they have a variety of tasks rather than a single task (Andrews & Pelz, 1976). This finding suggests that leadership identified as a role may actually increase the overall effectiveness of the scientist. Scientists who are trained specifically in leadership may not only increase their use of leadership practices but may also increase their effectiveness as a scientist (Day, 2003). Day's research leads to questions as to whether identifying leadership as a role for all employees would increase work effectiveness in general and could be the subject of future research.

Scientists define an effective leader as being caring and compassionate, technically accomplished, a good role model, and possessing managerial skills. Scientists view a bad leader as one who is abusive, exploitative, or unable to deal with conflict (Sapienza, 2005). Supervisors who attempt to help employees by using only technical skills actually decrease the employee's job satisfaction and job performance if the environment is already stimulating. In other words, in a stimulating environment, supervisors should not emphasize the use of technical skills in an attempt to improve job performance and job satisfaction. Concurrently, supervisors should not overuse administrative skills in an unstimulating environment (Cordero et al., 2004). In these situations, Cordero claims that people skills are most helpful in creating a stimulating environment in which to work.

Performance

Performance is directly related to supervisory practice (Jabri, 1992; Jordan, 2005; Keller, 2006). Effective leaders create an increase in job satisfaction and performance in their subordinates (Keller, 2006). Job satisfaction and performance increase when scientists feel that the task allocation by the leader is appropriate (Jabri, 1992). “Effective leaders in R&D project groups tend to inspire a sense of mission and purpose about the importance of the work being done, stimulate new ways of thinking and problem solving, and encourage group members to do more than what might normally be expected” (Keller, p. 498). Transformational leadership may be useful in studying professional organizations. “Effective leaders in R&D project groups tend to inspire a sense of mission and purpose about the importance of the work being done, stimulate new ways of thinking and problem solving, and encourage group members to do more than what might normally be expected” (p. 498).

There is a correlation between job satisfaction and job performance when task allocation is seen as appropriate, but no correlation between satisfaction and performance when allocation was seen as inappropriate (Jabri, 1992). Future research could incorporate more variables, including “conditions of goal setting, the processes that underlie task allocation decisions, and issues relating to control over task, control over others, and control over the work environment” (Jabri, 1992, p. 98).

A longitudinal study by the US Department of Energy found 37 factors that R&D workers find important that may increase their performance (Jordan, 2005). R&D workers cited 8 of the 37 factors to be most important. These factors include having a “clear research vision,” investing “in future capabilities,” making “sure staff have challenging work,” championing “long term foundational research,” having a “systematic way to identify new partnerships,” measuring

"the success of each project appropriately," ensuring "managers are technically competent," and researchers appreciate non-monetary rewards" (p. 32).

Autonomy, Creativity, and Innovation

Scientists are generally thought to prefer a high level of autonomy (Bailyn, 1987; Trevelyan, 2001). However, the type of autonomy is important in understanding satisfaction levels of the scientists. Bailyn describes two types of autonomy,

> strategic autonomy (the freedom to set one's own research agenda) and operational autonomy (the freedom, once a problem has been set to attack it by means determined by oneself, within given resource constraints)...Technical careers in the R&D lab should start lower on strategic than on operational autonomy, that operational autonomy show initial fairly rapid increase, which should be followed by increases in strategic autonomy, and that thereafter a number of different career paths should be available for technical employees (p. 129).

Trevelyan (2001) researched academic researchers as opposed to scientists in R&D laboratories in non-academic organizations. Trevelyan described two different types of autonomy, one where the leader is highly directive, yet not involved and the other where the leader is not highly directive, but very involved. Leaders who are highly directive with research scientists cause a decrease in satisfaction, but leaders who are non-directive and highly involved with valued input creates an increase in satisfaction which may also lead to an increase in creativity and innovation (Cardinal, 2001; Judge, Fryxell, & Dooley, 1997; Trevelyan, 2001).

A high degree of operational autonomy increases innovation. Scientists are typically goal-directed in biotechnology organizations and work best when the organization's management develops strategic objectives and context, but they require freedom to work independently within that context (Judge et al., 1997; Essex & Kusy, 2004). According to Essex & Kusy, "Create the loosest boundaries your organizational culture will allow, then let the mavericks out of the corral." (p. 128). "Balancing autonomy, personalized recognition systems, integrated

sociotechnical systems, and continuity of slack" have a major influence on whether or not there was a "goal-directed community in the R&D unit. Those firms that were the most innovative emphasized the importance of operational autonomy for the researchers, but retain strategic autonomy for top management" (Judge et al., pp. 76-77). Scientists exhibit many of the traits described by Essex & Kusy as "mavericks." Essex & Kusy point out that "the most important thing a leader of mavericks can do is to run interference for them, giving them some protection from the obstacles inherent in organizational life" (p.128).

Cardinal (2001) studied 57 pharmaceutical firms using "incremental innovations in the form of drug enhancements and radical innovations in the form of new drugs" (p. 19) as dependent variables. The use of input, output, and behavioral controls in R&D groups in U.S. pharmaceutical companies enhances radical innovation. Input and output controls enhance incremental innovation when behavior controls are not in place. One reason that controls may be necessary for enhanced innovation in the pharmaceutical industry is that "in the case of more uncertain technologies, learning occurs through error-induced discoveries. Looking at the evolution of several critical drugs and their corollaries…feedback loops created by both incremental and radical innovations are reciprocal, with both leading to subsequent learning" (p. 29).

Mumford's Propositions

Mumford et al. (2003) describes 37 actions or propositions that leaders must take to successfully lead scientists. These propositions are broken down into four levels: the individual level, the group level, the organization level, and the field level. These levels are further broken down into subcategories. The individual level is sub-grouped by propositions for direction, support, and role modeling. The group level is sub-grouped by propositions for group structure,

climate, and interactions. The Organizational level is sub-grouped by propositions for support, integration, and requirements. The Field Level has two sub-groups, scouting and representation. Mumford found that “eminent scientists are; 1) achievement oriented; 2) domineering, hostile, and competitive; 3) autonomous; 4) relatively unsociable or introverted and; 5) flexible or open minded” (p. 73). Scientists and scientific organizations are often faced with problems or issues that non-science companies are not. Performance requirements for scientific work (e.g., repeatability, and accuracy of results) may, in fact, be at odds with requirements in other functional areas, such as marketing and finance (which may value productivity and speed-to-market). Traditional leadership strategies are not always appropriate for scientific work. “The leader of scientists must be a boundary spanner, managing individuals, groups, the organization, and the field in such a way as to maximize the outcomes for all parties involved,” (p. 75).

Summary

To summarize, supervisory practice, performance, autonomy, and creativity are all important considerations when leading scientists. Scientists define effective leaders as being caring and compassionate, technically accomplished, good role models, and possessing managerial skills (Sapienza, 2005). Effective leaders increase job satisfaction and performance (Keller, 2006). Job satisfaction and performance increase when scientists feel that the task allocation by the leader is appropriate, the leader has inspired a sense of mission and purpose, stimulated new ways of thinking and problem solving, and have been encouraged to do more than what might normally be expected (Jabri, 1992; Jordan, 2005; Keller, 2006). Leaders should be highly involved, but not highly directive with research scientists and should support an environment conducive to creativity (Cardinal, 2001; Essex & Kusy, 2004; Judge et al., 1997;

Trevelyan, 2001). People skills are most helpful in creating a stimulating environment in which to work.

Supervisors should not use technical skills in an attempt to improve job performance and job satisfaction and should not over-use administrative skills in an unstimulating environment (Cordero et al, 2004). Traditional leadership strategies such as defining goals may reduce intrinsic motivation in R&D scientists (Hennessey & Amabile, 1988 a; Mullins & Sherman, 1993).

Scientists are more effective when they have a variety of tasks rather than a single task (Andrew & Pelz, 1976). Leadership identified as a role may increase the overall effectiveness of the scientist. Scientists who are trained specifically in leadership may increase their effectiveness as a scientist (Day, 2003). Scientists may not see the need for leadership and they may use skepticism as a subtle form of control over younger scientists and may over-idealize technology (Feldman, 1989; Owen-Smith, 2001). The use of input, output, and behavioral controls in R&D groups enhances innovation (Cardinal, 2001).Technical careers in the R&D lab should start lower on strategic autonomy than on operational autonomy, operational autonomy may show initial fairly rapid increase, and a number of different career paths should be available (Bailyn, 1987).

This chapter has first looked at the seminal literature on leadership strategies and then, more specifically, on leading R&D scientists. Conventional wisdom about leadership such as the importance of communication is also true for leading scientists. However, scientists prefer a higher degree of autonomy in setting goals, so conventional leadership strategies are not always directly appropriate to scientists. Because of the importance of creativity in research, leaders need to help foster an atmosphere and culture of shared communication and autonomy. The role

scientists themselves play in moving ideas from the laboratory to engage business leaders to take action is directly impacted by the leadership strategies used within the organization.

Moving Ideas: Research Bench to Consumer

To best understand how successful biopharmaceutical organizations are led, it is important to examine what scientists themselves do to move ideas from the laboratory to commercialization. This section of the chapter will examine the literature on how scientists move ideas from the laboratory to engage business leaders to take action. Key themes that arose from the literature include communication, networking, culture, and leadership. These themes have various levels of influence on the process, but communication and networking were specifically identified as having the most significant influence.

Biotechnology companies are based on the application of research discoveries. The application of research discoveries requires effective interdisciplinary teamwork and communication. Unfortunately, many scientists lack training in these skills. While the majority of authors state that communication is one of the critical elements required to move ideas out of the lab, most scientists are not trained in such communication skills and, even worse, the R&D culture may subtly inhibit their ability and desire to effectively communicate. Schön (1983) offers insight into the evolution of theory vs. practice and academia that is important in understanding scientists in the biotechnology arena. He states that the "concept of 'application' leads to a view of professional as a hierarchy in which 'general principles' occupy the highest level and 'concrete problem solving' the lowest…The application of basic science yields applied science. Applied science yields diagnostic and problem-solving techniques which are applied in turn to the actual delivery of services. The order of application is also an order of derivation and dependence. Applied science is said to 'rest on' the foundation of basic science. And the more

basic and general the knowledge, the higher the status of its producer" (p. 24). Because most scientists in biotechnology were originally trained as researchers, Schön's conception may be the foundation of the divide between science and business. On either side of this divide, the highest status belongs to basic research. The lowest status belongs to the application of the science. As a result, a subtle cultural discrimination exists in the biotechnology and biopharmaceutical industry that diminishes the value of applied science and its research

Schön (1983) states that

> this division of labor reflected a hierarchy of kinds of knowledge which was also a ladder of status. Those who create new theory were thought to be higher in status than those who apply it, and the schools of 'higher learning' were thought to be superior to the 'lower.' Thus were planted the seed of the Positivist curriculum, typical of professional schools in American universities, and the roots of the now-familiar split between research and practice (p. 37).

The foundation of the divide between science and practice began in the first research universities in the United States. Scientists who start their careers by studying biochemistry and cell biology enter a culture where 'hard science' carries the highest status. Along with this status comes a culture of not preparing scientists for the collaboration necessary to move science out of the laboratory.

For the scientist to effectively bring science out of the laboratory, he or she must engage in reflective collaboration with practitioners.

> In the kinds of reflective research I have outlined, researchers and practitioners enter into modes of collaboration very different from the forms of exchange envisaged under the model of applied science. The practitioner does not function here as a mere use of the researcher's product. He reveals to the reflective researcher the ways of thinking that he brings to his practice, and draws on reflective research as an aid to his own reflection-in-action. Moreover, the reflective researcher cannot maintain distance from, must less superiority to, the experience of practice…he must somehow gain an inside view of the experience of practice. Reflective research requires a partnership of practitioner-researchers and researcher-practitioners (Schön, 1983, p. 323).

This concept of collaboration is very different for scientists who typically prefer to keep to themselves or to stay involved with other scientists. Interestingly, a study of education levels among managers at life sciences organizations responsible for commercialization showed that 97% of these managers, at all levels, had an undergraduate or graduate life sciences degree (BioPlan Associates, 2003). This finding indicates that the great majority of people involved in product commercialization were originally educated as scientists and as such, they may not have experience in, or the desire, to collaborate with non-scientists.

Communication, Networking, and the Transfer of Knowledge

Communication is critical in moving ideas out of the laboratory (Allen, 1984; Argote & Ingram, 2000; Hirst & Mann, 2004; Hoegl & Gemeuden, 2001; Kivimaki et al. 2000; Nonaka, 1995; Wainer & Rubin, 1969). High levels of communication and interaction between departments is an important factor in innovation (Kivimaki et. al, 2000). High levels of internal communication contribute to innovation and it may

> facilitate the dispersion of ideas within an organization and increase their amount and diversity, which, in turn, may result in the cross-fertilization of ideas…Moreover, effective internal communication, in terms of close contacts between the personnel and work units participating in the innovation process, may contribute to success in the problem-solving, experimentation, and implementation stages of innovation" (Kivimaki et. al, 2000, p. 34).

However, interaction between groups predicts innovation less strongly than collaboration and too much interaction may actually interfere with innovation, if there are too many meetings and an overload of information. Collaboration means working together in a joint intellectual effort, whereas interaction is merely a mutual or reciprocal action. For scientists who may prefer to work alone, too many meetings may stifle creativity and the leader may want to help create an environment that limits the amount of meetings, but encourages collaboration.

Social interaction is importance in the dissemination of knowledge (Argote & Ingram, 2000; Nonaka, 1995; Yin & Gwaltney, 1981). The topic of communication between researchers and others in the organization does not need to be specific to the research at hand. Rather, the communication between researchers and practitioners raises each other's consciousness about the other and may have serendipitous effects (Yin & Gwaltney, 1981). Researchers may change the focus of their research based on dialogue with end-users. In addition, users may change future projections to reflect ongoing research. In this environment, acceptance of a new technology ultimately occurs (or does not occur) based on the effectiveness of ongoing communications. A better understanding of other's ways of thinking is important in building trust and further increasing communication.

"Knowledge held by individuals, organizations, and societies can be simultaneously enlarged and enriched through the spiral, interactive amplification of tacit and explicit knowledge held by individuals, organizations, and societies" (Nonaka, 1985 p. 34). Organization knowledge is more than organizational learning. It is the continuous incorporation and feedback of tacit to explicit knowledge throughout the organization. Nonaka states that the

> cross-functional teams in which experience sharing and continuous dialogue are facilitated by the management of interaction rhythms serves as the basic building block for structuring the organization knowledge creation process. The team is different from a mere group in that it induces self-organizing process of the entire organization through which the knowledge at the group level is elevated to the organizational level" (p. 24). Organizational knowledge is created when the organization faces a problem it has not

encountered before, and for which it has no immediate solution. This has been called "creative chaos" (Nonaka, 1985, p. 28). Through creative chaos, teams begin to self-organize with middle managers as the team leaders. Nonaka suggests the idea of "middle-up-down" management where self-organized teams begin to find solutions to the problems and true organization knowledge begins to be created.

> The main role of middle managers in middle-up-down management is to serve as a team leader who is at the intersection of the vertical and horizontal flows of information in the company. The most important knowledge creating individuals in this model are neither charismatic top managers nor the entrepreneur-like lower managers, but every employee who works in association with middle managers (p. 32).

Cross-functional teams (teams comprised of individuals from different functional areas within an organization, such as marketing and manufacturing) may lead to success in moving ideas out of the lab.

Knowledge transfer occurs through communication. “Knowledge transfer in organizations is the process through which one…is affected by the experience of another” (Argote & Ingram, 2000, p. 151). Much of the knowledge an organization has is “tacit and may not be easily articulated. Tacit knowledge may not be captured through the verbal reports often used to measure knowledge” (p. 152). Therefore, to facilitate knowledge transfer, organizations need to provide multiple means of communication within and between groups. “Explicit, codifiable knowledge that is embedded in technology has been found to transfer more readily than knowledge not embedded in technology. Similarly, technology transfer attempts have been found to be more successful when the technology is not complex and is well understood” (p. 158). This concept may help explain why it is difficult to move science from the laboratory because it is almost inevitably complex.

Other studies focus on leadership and communication and its effect on team performance (Hirst & Mann, 2004; Waldman & Atwater, 1994). Hirst and Mann (2004) reported on a longitudinal study to discover what communication variables most affected team performance. They evaluated 350 employees from 56 teams in four organizations. The study surveyed and evaluated both research managers and project customers and discovered that organization stakeholders have different perspectives of which factors influenced performance most

significantly. Project customers' ratings of performance were most influenced by communication safety. (In the study, communication safety was defined as participative decision making, power conflict, and open discussion. Power conflict was defined as "destructive rivalry between members of a team".) Task communication was the strongest predictor of both team member and research managers' ratings of project performance. "Boundary spanning is most effective when performed by the project leader not the team" (p. 147). Although leadership training programs may rightly teach leaders to stimulate debate and act as 'devil's advocate,' more attention to systemic issues is critical if there is to be a long-lasting cultural and behavioral change. Leaders must be held accountable and they must provide evidence of innovations being developed. "Organizations can enhance a leader's boundary spanning ability by implementing mentoring programs which socialize leaders to organizational norms, practices and develop leaders' influencing and championing skills" (p. 156). Important decisions will continue to be made informally through networks and leaders should be encouraged to build their networks. "In-house research forums and networking events particularly for peer groups provide an efficient means of developing leaders' intra-company links and the potential pool of knowledge sharing resources" (p. 156).

Success in R&D is highly dependent on leadership and championing. "Championing behavior is … an essential element of project success…championing seems to be even more necessary at higher management levels" (Waldman & Atwater, 1994, p. 242). Championing behavior involves key individuals who promote an idea throughout the organization. This finding is consistent with the work of Schön (1983). "Representation is also present as a related theme in that the effective leader is one who appreciates project members' scientific expertise and takes care of paperwork and other administrative details by upper management" (Waldman & Atwater,

1994, p. 242). This concept is supported by Bennis and Beiderman in their book *Organizing Genius* (2005) who also argue that for highly creative people to be successful, they need strong administrative support.

The opportunity to work closely to each other, or in proximity of each other, is important for scientists in networking and communication (Allen, 1984; Tidd et al., 2005). “Increased communication between R&D projects and other elements of the laboratory staff were in every case strongly related to project performance” (Allen, 1984, p. 123). Proximity may be one way to increase communication between scientists including having laboratories built around a central point to increase the chance of discussions, rather than in a linear hallway. At the same time, laboratories arranged in this central point fashion could decrease communication with other departments; this could be highly detrimental to moving ideas from the bench to consumer.

Tidd et al. (2005) found three factors associated with success in a study of 94 biotechnology start-ups: “location within a significant concentration of similar firms, quality of scientific staff (measured by citations), and the commercial experience of the founder. The number of alliances had no significant effect on success, and the number of scientific staff in the top management team had a negative association, suggesting that the scientists are best kept in the laboratory. Other studies of biotechnology start-ups confirm this pattern, and suggest that maintaining close links with universities reduces the level of R&D expenditure needed to increase the number of patents produced, and moderately increases the number of new products under development. However, as with more general alliances, the number of university links has no effect on the success or performance of biotechnology start-ups, but the quality of such relationships does” (p. 551). As mentioned previously, most biopharmaceutical companies are started by scientist/entrepreneurs and most of them fail.

> The member-member or social network also plays an important role in knowledge transfer. The social network can link organizational units to new sources of knowledge and aid interpretation of the new knowledge. More research is needed on the properties of social networks that facilitate (or impede) transfer. Future research should also examine the strong group identities that are often associated with dense social networks in organizations. The identification with a social unit can lead to in-group favoritism where the members of one's own group are perceived much more favorably than members of other groups. Research is needed on how this in-group favoritism can affect knowledge transfer in organizations (Argote & Ingram, 2000, p. 164).

In-group favoritism may be particularly true with researchers versus other groups within an organization.

> Members may identify primarily with their own work group, with the department in which their group is embedded, with the larger division of which the department is a part, or with the firm. An organization where members identify most strongly with their work groups may have more difficulty transferring knowledge across groups than an organization where members identify mainly with the superordinate organization (p. 165).

The authors could have been describing researchers in biotech organizations. For science to be successfully transferred from the lab, it is important for laboratory scientists to identify with the larger organization and not just other researchers.

Elements of Leadership and a Culture of Success

Boundary spanning and commercial experience of the founder have been shown to be elements of leadership important to moving ideas from the lab (Hirst & Mann, 2004; Tidd et al., 2005). Others research shows that management action directly impacts project performance (Elkins & Keller, 2003; Shim & Lee, 2001). Innovation and movement of ideas out the lab are part of a process that is culture-dependent, but is also directly related to actions of the leader. "The leaders should also boundary span with important constituents outside the project group, such as managers and personnel in marketing, manufacturing, and operating divisions, as well as with customers from outside the firm. This kind of activity to champion the project can be critical to the survival and success of the project" (Elkins & Keller, p. 601).

Rational tactics for influencing team members by R&D project leaders have a positive effect on the projects (Shim & Lee, 2001) These tactics include providing a clear understanding of why an action or a goal is important. Project leader activities may frequently include championing ideas across organizational boundaries to garner support and resources. Empowered employees may be a means of overcoming some of the problems of managing knowledge workers. However, empowered employees need direction and leadership if their efforts are not to be wasted. On the other hand, they also need a level of autonomy in how their work is actually carried out (Judge et al., 1997).

Tampoe (1993) researched motivation and found that financial, personal growth, operational autonomy and task achievement are all key motivators of scientists. However, even when financial motivators are met, the need for personal growth, operational autonomy, and task achievement still exist. For biopharmaceutical companies to succeed, managers and leaders must stay closely in tune with the scientists to best understand the employee's motivation.

Another study found that the most successful entrepreneurial scientists have a high need for achievement and have a high degree of self-efficacy (Wainer & Rubin, 1969). Entrepreneurs with the highest need to achieve are often the most successful based on sales.

> It may be that for those individuals who only have a moderate level of need for achievement, a high level of need for affinity enables them to form close interpersonal relationships with their colleagues. In this way, the moderate need for achievement individual may be able to acquire the assistance he needs from his colleagues, some of whom may have a higher level of need for achievement than he himself has (p. 184).

For biopharmaceutical companies to have a higher probability of success, the leadership should have a high need to achieve.

Teamwork is also critical success factor in innovation (Hoegl & Gemeuden, 2001). "Managing innovation to move ideas from the laboratory is more than direct leadership, but also

of orchestrating collective action of teams" (Stoker, Looise, Fisscher, & de Jong, 2001, p. 1141). Very little research has been done on the role of the leader in biotechnology organizations and the leader's effect on the success of organization in terms of research and development of new ideas. "Self-managing teams are responsible for some part of a production process, and they function with significant autonomy" (Stoker et al., p. 1143). Those scientists with a high degree of self-efficacy believe they can achieve results and are often high performers.

In summary, scientist-leaders should, boundary-span outside the project group to champion the project, empower their employees, yet also provide clear direction and expectations of their project group, have a high need to achieve, understand what motivates the individuals in their project group, and recognize the importance of self-managing teams.

Culture of Research versus Practice

Key themes in moving ideas from the laboratory to engage business leaders to take action that are supported by the literature are communication, networking, culture, and leadership. However, there is such a strong cultural bias that favors research over practice, for scientists to effectively move ideas from the lab they must work within a culture that supports this effort. Because the culture of an organization is directly influenced by its leadership, the nature of the organization's leadership is a critical component in the ability of scientists to move ideas from the lab and in developing a culture that supports or inhibits effective communication across boundaries. An organization's culture is certainly influenced by factors other than leadership, but the core of company culture comes from its leadership. Therefore, further study is needed to understand the role of the leadership and how it influences cross-boundary communication within the organization.

Moving ideas from the laboratory to commercialization involves complex interactions within the organization. To truly understand what happens in successful biopharmaceutical organizations, new research should focus not only on the scientists, but also the collective organization processes that include leadership, communication, networking, and organizational culture. These processes, in particular the organization's culture, are affected by the practices of the leader. The culture of the organization determines the level of communication and networking required to support a successful environment.

Leadership practices have not, as yet, been explored in biopharmaceutical companies. Because most biopharmaceutical companies are founded by scientists, the research should specifically look at those companies with a scientist/founder/leader. Multiple case studies involving interviews and archival data would provide important knowledge for the industry. Allen (1984) stated that when doing research on research scientists one must note that "each piece of work is unique" (p. 12). Because there can be no exact replication in the research, it "makes performance more difficult to measure because there is no common denominator among projects to provide a basis for comparison" (p. 12). Allen points out that this lack of comparability makes the case study method a good choice for future research.

Summary of Findings

The literature clearly defines important strategies that leaders should considering using to help guide their company to success. These strategies include: A guiding vision, creating a learning organization, excellent communication, active listening, a sense of urgency, embodying the story, viewing the organization as an entire system, and creating an atmosphere or culture that is a holding environment for employees. However, when leading scientists and biopharmaceutical organizations, effective leaders also inspire a sense of mission and purpose.

They are caring, compassionate, technically accomplished, good role models, stimulate new ways of thinking and problem solving, inspire followers to do more than they might otherwise do, and have good managerial skills. Task allocation should be appropriate, leaders should be highly involved, but not directive and have good people skills.

Scientists should be given a variety of tasks, including leadership opportunities and training, because this may increase their effectiveness as scientists. Leaders should be aware that scientists may not see the need for leadership and they may use skepticism as a form of control. However, management action directly affects project performance. Input, output and behavioral controls should be in place to enhance innovation and scientists should be given a variety of career paths.

Moving ideas from the laboratory to the customer requires high levels of communication. The higher the level of interaction between departments the greater the rate of knowledge transfer. Prior commercial experience of the leader has been shown to also be important. Innovation and movement of ideas out the lab are part of a process that is culture-dependent, but is also directly related to actions of the leader.

This chapter has examined leadership practices and strategies for leaders of organizations and specifically of R&D scientists. The chapter has examined ways scientists engage business leaders to take action. The chapter has also discussed the life cycle of the organization and the suggestion that the same leader may not always be the best person to lead the organization as it moves forward through different development phases toward maturity. However, there are several examples of scientist founders who have successfully led biopharmaceutical organizations to maturity. Questions remain about which leadership practices of scientist/leaders in successful biopharmaceutical organizations are most effective. The following sections will

describe the processes involved in developing a biopharmaceutical product and also describe specific examples of success and failure in the biopharmaceutical industry.

Success and Failure in Drug Development

Many of the biotechnology companies in the 1980's and early 1990's attempted to model their business strategies based on expectations of becoming fully-integrated pharmaceutical companies, or FIPCO's. A fully integrated company researches, develops, manufactures and markets its products. Because of the insufficient funding available to these organizations, and inexperienced management, few companies were able to actually become fully vertically integrated. Amgen, Genzyme and Genentech are some of the few fully integrated biopharmaceutical companies today.

Most biotechnology companies formed in the early stages of the industry's development either merged or liquidated. During this time, the optimism surrounding the potential from biotechnology created a positive investment climate. However, as the optimism waned, investment funding slowed. At the same time, because so many start-up biotechnology companies were attempting to fully integrate, the amount of available funding became diluted, "limiting the support that each company could attain," (Friedman, 2006, p. 13). There was also a strong need for both technical and business managers with expertise in the science and the commercial aspects of drug products. However, most pharmaceutical managers were skilled in either commercialization or drug discovery, but not both (Friedman, 2006). There was also the problem that these managers needed to be experienced in many stages of drug development.

There are five stages of drug research and development, both for traditional pharmaceutical drugs and biopharmaceutical drugs. These include target identification, lead compound generation, preclinical trials, clinical trials, and regulatory approval, and marketing.

For companies to successfully develop drugs, their managers, collectively, must have experience in all five.

Stages of Drug Research and Development

Traditional pharmaceutical drugs are typically chemically created small molecules that can be taken orally in a pill form. Biopharmaceutical drugs are generally large protein molecules that can become degraded in the human digestive system**.** As a result, different delivery systems are often required for biopharmaceuticals, such as injection, skin patches, or inhalation. “Because alternative delivery systems allow for better tissue targeting, smaller doses, and potentially fewer side effects than orally administered drugs, overcoming the challenge of drug delivery can present new opportunities,” (Friedman, 2006, p. 32).

Identify target. The first step in the drug research process is target identification. Identifying and validating targets involves the process of “finding the specific biochemical pathway, receptor, protein, or gene that serves as a suitable point for intervention in a disease process,” (Pisano, 2006, p. 45). At this stage, in vitro (in a laboratory vessel) or animals are used to test the target.

Lead identification. There are several ways to identify possible new drugs or leads. Methods for drug discovery typically involve purifying naturally occurring compounds, synthesizing new drugs, or finding new uses for existing drugs with beneficial side effects. An example of a new use for an existing drug was Viagra as a treatment of erectile dysfunction. This new use was discovered during clinical trials for the drug’s treatment of angina (Friedman, 2006 p. 34).

Pre-clinical trials. Safety and efficacy of a potential new drug must be evaluated and tested at many stages. Prior to human testing, drugs are tested both in vivo (in animals) and in

vitro. This process may take a year or more. “Even though the compound is thoroughly tested in the laboratory and in animals, when used in humans, unforeseen problems may arise. A recent example is the use of gene therapy techniques in humans. Gene therapy frequently fails when introduced into human beings even though trials in cultured cells were successful” (Friedman, 2006, p. 35).

Clinical trials. There are generally considered to be three phases of clinical trials, although a fourth phase monitors post-marketing of the drug and also looks for new treatment indications. Phases 1, 2 and 3 involve testing in humans. Phase 1 clinical trials evaluate drug safety using a small number of human subjects. These are typical normal volunteers, but the subjects may be patients. Phase 2 clinical trials test a larger number of patients, and are mainly concerned with safety and efficacy. These trials typically consist of a few hundred patients. Phase 3 clinical trials are conducted, sometimes, with hundreds or thousands of patients and are mainly focused on efficacy of the drug (USFDA, 2007; Friedman, 2006; Pisano, 2006). “Drugs administered in clinical trials must be produced using current good manufacturing practices (cGMP), ensuring proper control of facilities, raw materials handling, manufacturing, and associated documentation. Clinical trial data is submitted to the USFDA as part of a New Drug Application (NDA) or Biologics Application (BLA),” (Friedman, 2006, p. 36).

USFDA approval, marketing and sales of the drug. It can take 10-15 years to receive USFDA approval of a new drug and, when the costs of failed drugs are considered, successful ones can cost over $800 million to bring to market (Tufts, 2007). The USFDA is mainly concerned with safety and efficacy of new drugs, but side effects are also of concern. In certain situations, the USFDA will approve a drug with detrimental side effects if there are no alternative or better treatments and the disease is severe enough to warrant it (Friedman, 2006).

Before a company begins clinical trials, the product is usually given patent protection. Because of the time involved in clinical trials, there are typically around 12 years of patent life remaining on a new drug once it has received USFDA approval. After approval, companies work quickly to penetrate the market and generate revenues.

> The emergence of competing products and looming patent expiration dates motivate the development of alternative drug forms and formulations to leverage established brands, and modification of marketing methods to extend sales. Some firms specialize in modifying patented drugs, capitalizing on the negative specter of patent expirations, patenting their modifications, and licensing them to pioneers as a means to preempt generics, (Friedman, 2006, p. 39).

Examples of Success and Failure

The high risk and high cost of developing biopharmaceutical drugs mean most biopharmaceutical companies are not successful. According to Friedman (2006), the most successful biopharmaceutical companies chose protein platforms whose functions were already known and used a directed design strategy. Examples of these companies include Amgen, Genentech, and Genzyme.

Genentech. One of the first biotechnology companies, Genentech is also one of the most successful. Founded in 1976, the company now has over 10,000 employees and revenues of over $9 billion annually (Contract Pharma, 2007). Since its founding, Genentech has consistently maintained its entrepreneurial culture. Friedman (2006) describes four traits of the Genentech culture that are responsible for its success. The company maintains entrepreneurial leadership by hiring excellent scientists and "driving scientific initiative through self-selected projects. Genentech encourages its researchers to spend 25% of their time on projects of their choosing" (p. 154). Genentech uses open technology and has in-licensed over 100 technologies. Product development is boundary-less and cross-functional teams are assembled for each new product. These teams consist of scientists, relevant business areas and key stakeholders. Genentech also

maintains a strong focus on its core mission and the company regularly rejects even promising projects that are outside their expertise.

> The history of Genentech serves as a paradigm for biotechnology product development and corporate growth. Genentech was founded to exploit a novel scientific innovation. Without sufficient resources to fully develop and commercialize its first product, Genentech licensed these rights to a larger partner. Tapping revenues from early products enabled Genentech to develop sufficient bulk to fully research, develop, and commercialize its own products, (Friedman, 2006, p.11).

Amgen. Amgen is the world's largest biotechnology company and is ranked as the number one biopharmaceutical company based on revenues in 2006 of over $14 billion (Amgen, 2007; Contract Pharma, 2007; Herper & Langreth, 2007). Amgen makes drugs to combat anemia, arthritis and cancer. In 2006, two of Amgen's products were the top-selling biotech drugs, Aranesp and Epogen, both for the treatment of anemia (Reuters, 2007). With over 14,000 employees, Fortune Online rated Amgen as one of the top 100 companies to work for in 2007 (Fortune, 2007). BusinessWeek magazine listed Amgen, Inc. as the number four company in the United States in terms of innovation and investment to create future wealth (BusinessWeek, 2004). In 2003, over half of Amgen's spending was on R&D.

Gordon Binder was President and CEO from 1988 until 2000. In a 1996 interview, Binder discussed Amgen's success and stated that "among the key ingredients [to success] are teamwork, risk-taking and the pursuit of excellence" (Arnaout, 1996). Binder stated that all levels of employees are treated the same and the culture at Amgen is where risk-taking is encouraged. "Every time we took a risk, it paid off. And when we didn't, it hurt us," Binder also stated that work should be fun and not stressful. He emphasized that as long as working at Amgen is not stressful, the company would be successful. Another key element to Amgen's success, according to Binder, is that "The people who do the work should help plan the work,"

The enthusiasm this creates for people who make the plan more than makes up for the time it takes to come up with that plan."

Genzyme. Genzyme, a biopharmaceutical company founded in 1981, now has over 9,000 employees. Genzyme uses a non-traditional strategy for drug development and focuses on rare, genetic disorders. In 1983 the Orphan Drug Act was initiated [The Orphan Drug Act (P.L. 97-414) amended the Federal Food, Drug and Cosmetic Act (FFDCA) as of January 4, 1983.]. The Act grants exclusive sales rights for seven years to companies who develop drugs for small patient populations (less than 200,000 patients). Most drug companies want to develop drugs for large patient populations, but being provided exclusive marketing rights for treatments for rare diseases makes the market more commercially attractive to companies that otherwise would not risk their R&D resources for such small markets. Genzyme focuses solely on orphan drugs. Their first drug, Ceredase, for the treatment of Gaucher's disease, won USFDA approval in 1984. Genzyme charges some of the highest drug prices in the world, but works closely with insurance companies and patients to make sure anyone who needs the drugs receives them. The cost of Cerezyme is $200,000 per year, per patient (Calabro, 2006). The company does not deny anyone access to the drugs and in many cases gives the drugs away for free. The high price for Genzyme's drugs draws substantial criticism from those who argue that the cost of drugs in general is too high. Despite building pressure to bring costs down, Genzyme argues that R&D and manufacturing costs warrant the high price of their drugs. Approximately, 4,500 people take Cerezyme each year, and about 450 receive the drug for free (Calabro, 2006). As the drug becomes available in expanding markets such as China, questions remain about the ability of Genzyme to continue to offer such an expensive drug for free.

Genzyme is listed by Fortune magazine as one of the top 100 companies in which to work in 2007 (Fortune, 2007). The focus of the organization is on global manufacturing, rather than R&D, where most biotechnology organizations focus their resources. The organization is highly decentralized, with highly autonomous divisions (Higgins, 2005). According to Genzyme's CEO, Henri Termeer, "We are proud of our unique company culture that encourages employees to be entrepreneurial and to seek to make a difference in the lives of patients with serious diseases," (PRNewswire, 2006). Scientists rate Genzyme rated as one of the top ten pharmaceutical/biotech companies for which to work. According to a 2006 survey by Science magazine, companies were rated on attributes such as "treating employees with respect, whether work-culture values are aligned with employees' personal values, and whether the company has a clear vision of the future. Genzyme has received this top honor for three consecutive years and has earned high ratings for its social responsibility, innovative leadership and quality research," (PRNewswire, 2006).

Amgen, Genentech, and Genzyme are considered highly successful, not just based on their annual revenues, but because they have a company culture that is conducive to success. Yet, despite the good science being developed at most biotechnology companies, many continue to fail.

Failure

Most biopharmaceutical companies fail due to lack of funding and available cash, unexciting, or unpromising science, negative results from clinical trials, or simply lack of demand for the product. "Only 54 of 342 publicly traded American biotech companies were profitable in 2006," (Pollack, 2007). The Motley Fool, an investment consulting firm, examined 41 biotechnology companies that went public in 1995-1996. Of these 41 companies, only 25

were still in business. The remainder either went bankrupt or were acquired. “Over half of those acquired were sold for less than what it was worth on the day of the IPO,” (Travers, 2005). Of the 25 that were still in business in 2005, only six were profitable. “ ‘In the end it was a vicious circle. To get additional financing, there tended to be false expectations that were difficult to deliver, which, combined with some weak science, led to a disillusionment for key investors which caused everything to unravel,’ recalls Thomas R. Sharpe, former president of OsteoArthritis Science Inc.” (Rosenberg, 1996).

High burn rate. Many of the biotechnology companies that were founded in the early 1980s and are still in business, have yet to be profitable. A company that is not profitable, but spends more money than it brings in, is considered to have a burn rate. For example, Xoma, ImmunoGen, Repligen, Immunomedics, Biopure, and Cytogen are not yet profitable (Pollack, 2007). Other organizations such as Cell Therapeutics, Dendreon, Seattle Genetics, Targeted Genetics, and ZymoGenetics are all over ten years old and have spent between $170 million and $928 million since their inception (Cook, 2007).

Lack of demand. Genetic Savings & Clone, a biotechnology company that sold cloned pets, folded at the end of 2006 because of low demand. Since its opening in 2000, the company created five cloned cats, but sold only two. One was a cloned kitten from a cat whose owner had the cat for 17 years and was saddened over its death. She paid $50,000 for the cloned kitten. The cloning of pets raised strong ethical debates among animal rights activists and the Humane Society. “ ‘It's no surprise the demand for cloned pets is basically nonexistent, and we're very pleased that Genetics Savings & Clone's attempt to run a cloning pet store was a spectacular flop,’ said Wayne Pacelle, head of the Humane Society of the United States. ‘It's not just a bad

business venture, but also an operation grounded on the misuse of animals,' " (Associated Press, 2006).

Calgene developed the first genetically engineered food, the Flavr Savr Tomato. They inserted a gene into tomatoes that slowing ripening, so the tomatoes would last longer on the grocery shelf. Farmers could allow the tomatoes to stay on the vine longer, resulting in a better tasting tomato. Flavr Savr tomatoes were introduced to the market in 1994. They were removed from the market a few years later, not because the tomatoes did not live up to the promise of a longer shelf-life, but because the tomatoes were priced very high and consumers did not see the tomatoes as worth the additional cost. As a result, Calgene could not make a profit (Friedman, 2006).

Failure in clinical trials. Occulon Corp. developed a drug for the treatment of early stages of cataracts that was expected to reduce Medicare spending on cataract surgery. However, in clinical trials the drug did not live up to its promise. "'We simply realized that what we had just did not work well,' said Lawrence Kinet, Occulon's former president. 'It was not worth continuing,'" (Rosenberg, 1996). Similarly, Telor Ophthalmic Corporation's vision drug also failed in clinical trials. After the failed trials, the "company simply ran out of money and closed its doors…after going through $21 million in venture financing in five years," (Rosenberg).

Strategies to prevent failure. Poor results from clinical trials can be devastating to a biopharmaceutical organization. However, companies often have other assets they can use to continue functioning. These can include cash from investors, intellectual property, in-house expertise, and the value of other drugs in their pipeline**.** Five San Francisco companies, Nuvelo, Inc., Telik Inc., Renovis Inc., Dynavax Technologies Corp. and Threshold Pharmaceuticals all had their lead drugs fail in clinical trials during 2005-2006. "Nuvelo's shares fell 79 percent after

it reported the trial results. The other companies saw similar plunges in their stock prices. But biotech companies often manage to reinvent themselves, even after the bleakest news. Because major setbacks are so common in medical technology, experienced executives and financiers have developed ways to get companies back on track." (Tansey, 2007) Companies can conduct new clinical trials, or they can look for a merger partner or buyer for the company. Companies will also try to have cash reserves on hand. "Nuvelo is a case in point. It has $153 million in the bank, which gives it time to regroup while it works on several early stage drug candidates" (Tansey, 2007).

A biotech company with promising early stage research, but whose leading product fails, still has options. The company "can merge with a company that is close to marketing a drug but has a dry pipeline. The combined company has a better balance of risks and an improved chance of steady growth," (Tansey, 2007). Corgentech merged with AlgoRX after Corgentech's lead drug failed in clinical trials. CancerVax was taken over by Micromet AG, after CancerVax's melanoma vaccine failed in Phase 3 clinical trials. According to Nuvelo's CEO, Ted Love, "There are only two kinds of biotech companies -- those that have had disappointments and those that will have disappointments in the future. The successful ones are those that work through their disappointments," (Tansey). The difference between success and failure is often the ability of the senior management of biopharmaceutical firms to navigate the permanent whitewater of the industry.

The following chapter describes the methodology used for exploring leadership practices of successful biopharmaceutical companies with scientist, founder leaders. I used an exploratory, multiple case study approach to begin to shed light on this previously un-researched area. I used interviews, archival data, and questionnaires for data collection. I analyzed the data using the

high-level topic areas proposed by Mumford et al. (2003), including the individual level, the group level, the organizational level and the field level. I used NVivo software to analyze the data and to determine whether themes exist between organizations. The next chapter expands on the methodology for this work.

Chapter III: Methodology

Purpose of the Study

The purpose of this study is to better understand success in biopharmaceutical organizations and determine how scientist/founders leaders affect this success. Because commercial success for biopharmaceutical organizations is attained only after many years of research and development, clinical trials, and lengthy regulatory approval processes, I have applied Pisano's (2006) definition of success to the biotechnology industry. "Success is defined as how effectively an organization or industry uses the capital it raises, and more specifically, how well it creates true value from its activities. Ultimately, value creation and capture are what matters" (p. 162) Pisano argues that existing approaches to business and organizations are not satisfactory for biotechnology organizations. "Organizational and institutional innovations are needed in order to unlock the potential of biotechnology" (p. 202). The biopharmaceutical industry is a subset of the biotechnology industry and Pisano's argument for value creation applies to biopharmaceuticals as well.

My primary guiding question was "How do some scientist/founders lead their successful biopharmaceutical organizations?" I wanted to better understand how scientist/founders establish the institutional context that creates the conditions for success. I used a multi-case method to research three scientist/founder leaders of successful biopharmaceutical studies and the senior executives within the organizations to attempt to answer my research question. Three outside experts/consultants were also interviewed who have extensive experience working with scientist/founders of successful and unsuccessful organizations

Justification for the Use of the Case Study Method

The use of the case study method to answer the research question is justified by three well-known scholars in the field of case study research, Yin, Stake and Boje. According to Yin (2003 b) who writes: “A case study is an empirical inquiry that investigates a contemporary phenomenon, within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident” (p. 13). The case study method should be used if the contextual conditions of the situation may be pertinent to the phenomenon of study. Yin also states that a case study is the right choice of inquiry when the researcher wants to know how and why. A case study addresses a descriptive question, such as what happened, and is often used when the researcher has little or no control of the events (Yin, 2003 b, p. 5). As the researcher, I was an outsider to the organizations studied and will not directly affect its success or failure.

According to Stake (1995), the researcher plays the role of interpreter in a situation and attempts to build or construct new meaning. Stake describes three realities in one’s conceptualization of the world. The first is the external reality that is our basic interpretation of stimuli. The second reality is our interpretation of those stimuli. The third reality is “a universe of integrated interpretations, our rational reality” (p. 97). By triangulating the data collected from one-on-one, unstructured interviews with the leaders, and through archival and secondary data, I analyzed and interpreted the data to determine what themes arose. A research team of three PhD graduate students provided additional analysis of my evaluation of the interview data. Two of the research team members are graduate students in the Antioch University PhD in Leadership and Change program and have been trained in interview data analysis. The third team member is a PhD Candidate in Medical Anthropology, from American University, and is an expert in the use of NVivo software and data analysis.

The cases are written as an antenarrative. David Boje (2001) states that in an antenarrative, “The focus is on the analysis of stories that are too unconstructed and fragmented to be analyzed in a traditional approach...Stories in organization are self-deconstructing, flowing, emerging and networking, not at all static” (p. 1). Boje defines an antenarrative as a pre-narrative where the researcher attempts to recontextualize the actual story or case. The case studies evolved over time, from many different perspectives and are told from many sources. I initially interviewed leaders of successful biopharmaceutical organizations, and deeper analysis and meaning making came from reflection, analysis and through deconstruction. According to Boje, “The analyst joins in the antenarrative by becoming part of the ongoing textual deconstruction of interpenetrating processes and weaves of reconstructing, unraveling and constructing stories” (p. 10).

Finally, I used multiple cases rather than a single case. As Yin (2004 a) points out, multiple cases may help strengthen the findings from the entire study, as they may be “replications of each other, deliberate and contrasting comparisons, or hypothesized variations” (p. 6). The cases I researched are confirmatory, that is, replications of successful organizations.

Purposeful Sampling--Leaders and Organizations

While my original intent was to research only for-profit biopharmaceutical organizations, I have also included a non-profit in the sampling set for the reasons stated below. I began my sampling by compiling a list of twelve for-profit biopharmaceutical organizations with scientist/founders who have products in clinical trials. The list was short because although many scientists have founded biopharmaceutical organizations, very few met my criteria of success (creating value as identified by having a strong product pipeline and products in clinical trials). I was familiar with the founders of two of these for-profit companies. One of the two founders that

initially agreed to participate backed out after he found out I would need to interview the senior executives in the company. I then called and e-mailed the remaining companies on the list. After multiple calls and e-mails a second scientist/founder agreed. However, I was having difficulty gaining access to a third organization. I explained the problem of gaining access to my dissertation committee chair and we decided I should broaden my search and use a product development partnership (PDP) organization.

With the number of global healthcare crises continuing to climb, and with the gradual shift in Western countries' policies toward the plight of developing nations, the pharmaceutical industry has slowly shifted from an exclusively for-profit model to one that provided benefits to a greater range of populations. Product development partnerships (PDPs) are a new type of company created because of the high expenses involved in developing new drugs and therapeutics. Many large pharmaceutical organizations do not want to invest in drugs that are for markets in under-developed countries because they are high risk and will not generate a substantial enough profit. However, some altruistic foundations and governments are willing to invest, but they require a product be developed and distributed as quickly as possible. This requirement results in a more results-oriented business focus in the PDP than in most non-profit organizations. The research, development, marketing and regulatory issues involved however are the same as in for-profit companies. As this is exploratory research, my chair and I decided that a PDP would be a good choice to help better understand the nature of success in all types of biopharmaceutical organizations.

Ultimately, I interviewed scientist/founders of three biopharmaceutical organizations that have multiple products in clinical trials. Company A and Company B are for-profit organizations, and Company C is a product development partnership. Company A and Company

C are smaller organizations with fewer than 100 employees and products in Phase 2 clinical trials. Company B is a large, successful organization that has a rich pipeline of products in all phases of development and it generates a profit. Company A and Company C are considered successful because this research defines success in this market to mean creating value; and value is created by having products enter clinical trials.

To better triangulate the data, after I had completed the interviews with the companies, I interviewed three outside expert consultants who have extensive experience in biopharmaceutical organizations with scientist/founders. Consultant 1 is an executive leadership coach and organization consultant to senior executives in biotechnology including scientist/founders who have successfully led their organizations. Consultant 2 is a venture capitalist who invests in biopharmaceutical organizations, some of which have been highly successful with scientist/founders. Consultant 3 is currently a scientist/founder of successful biopharmaceutical companies and he also consults with venture capitalists to help them decide in which companies to invest.

Data Collection and Procedures

My primary method of data collection was one-on-one interviews with the scientist/founder leader. The case study method of interviewing requires the use of a template of ideas and open-ended questions, rather than a specific list of questions. “An exploratory interview is open and has little structure. The interviewer in this case introduces an issue, an area to be charted, or a problem complex to be uncovered (Kvale, 1996, p. 97). “Case study interviews are of an open-ended nature, in which you can ask key respondents about the facts of a matter as well as their opinions about events” (Yin, 2003 b, p. 90). I used key words including *envision, leadership* and *success* as touchstones to keep the conversation on track. (See

Appendix B for the interview template used.) I conducted all interviews in person except for the consultants, whom I interviewed by telephone. The interviews were recorded using a digital recorder and were transcribed by a professional transcription service. Before I began the interviews, I received permission from the CEO to interview senior executives in the organization.

At the beginning of the interview, I asked all interviews if they agreed that the interview could be recorded and to sign informed consent statement. (See Appendix C for a copy of the form). I spent a brief time discussing a general overview of the organization, such as the nature of the company, the leader's background, etc. The leaders of the organizations are former bench scientists from a research laboratory environment and, as such, it was important to build trust by not engaging them too quickly in narrowly focused discussions. I did not spend much time at the beginning addressing softer issues such as the leader's feelings or opinions. As the interview progressed, I transitioned back to the touchstone words and to begin to gather data from the interviewee that would be useful in the final analysis. After I built rapport, I explained to all the interviewees that the data would be disguised and aggregated so that their confidentiality would be maintained.

I used triangulation to verify my findings. Triangulation is an important tool for verifying and validating the data sources and making the research conclusions more plausible and acceptable in the research community.

I kept a reflective journal during the data collection period and coded the data in such a way that a research team was able to follow the analysis process. The journal provided a record of the events that occur during the data collection and helped explain any unexpected variations that occurred during the collection.

I used secondary resource material as another method of data collection. Before each interview, I researched the leaders and the organization to ensure I had a good understanding of both. I used public documents and other published material in newspapers and magazines to build a foundation of understanding for the organization.

All data were stored electronically on a fingerprint-protected laptop computer and backup files were kept on a portable drive that was stored in a locked drawer. All hard copies of the data were also kept in a locked drawer and secure at my office. All names were removed from the transcriptions and were replaced with identifying numbers. A separate list of participants and identifying numbers were kept in a separate locked file.

Coding and Analysis

According to Creswell (2003), data analysis and collection is "an ongoing process involving continual reflection about the data, asking analytic questions, and writing memos throughout the study. It is not sharply divided from the other activities in the process, such as collecting data or formulating research questions," (p. 190). I had the interview data professionally transcribed and imported into NVivo 7 software from QSR International. Before I began coding the data, I reviewed the transcriptions to "gain a sense of the whole," (p. 192). I then clustered similar topics, and with NVivo software, I was able to edit and annotate the transcriptions of the interviews and my notes, memos and other documents after they have were imported. The data were analyzed to find relationships between items, processes and people. I looked for codes that I expect to find, but I also looked for "codes that [were] surprising, and codes that address a larger theoretical perspective in the research," (Creswell, p. 193). The software also allowed me to easily graphically display my results, which again, allowed me to identify relationships visually that I might have otherwise missed.

As mentioned, I kept a reflective journal throughout the data collection, and analysis process. To check for accuracy, I used use Creswell's suggestions of "triangulating data sources, member-checking, (and) detailed description" (2003, p. 220). A final step in the analysis was interpreting and making meaning of the data and lessons that I learned. The analysis was necessarily influenced by my tacit knowledge and experiences; however, the analysis was also done recognizing these known biases.

Suggested Validation of the Accuracy of the Findings

According to Creswell (2003), validity in case study research provides a way for the reader to better discern accuracy of the findings from the researcher. Creswell suggests eight strategies that can be used to check the accuracy of the findings. These strategies include: triangulation; member-checking; rich, thick descriptions; bias clarification; explaining negative or discrepant information; the researcher spending a prolonged time in the field; peer debriefing; and the use of an external auditor (p. 196). I used all of these strategies to varying degrees. I used triangulation and member-checking, thick descriptions, audit trails, I explain the limitations of the study, I debriefed with my peers (particularly during the analysis and coding of the data), and spent as much time in the field with the organization as permitted by the leader.

Researcher bias. I have been a professional in the biotechnology industry for over 25 years and because of this I brought biases created from my past experiences. Some of these biases include my personal perceptions of what leaders may do to help create conditions for success in their organization. In addition, I have had varying degrees of personal interactions and experiences with two of the organizations I interviewed. These perspectives have evolved from my own experiences and from the literature I have extensively read. Because of my potential biases, I had three graduate students verify my coding and analysis of the data as a form of

checks and balances to my analysis. The graduate students were all trained in data analysis as part of their education in their PhD programs. I also used as many data sources as possible to verify my findings.

Triangulation and member checking. I used triangulation to, as Yin (2004 a), states, "establish converging lines of evidence to make your findings as robust as possible." (p. 9). My triangulation plan included interviewing the leaders and then, from the data collected in the interviews, I interviewed other senior executives in face-to-face interviews. I then interviewed three outside experts in success and scientist/founders. I used secondary data sources to verify as many facts and perceptions as possible. I also used member-checking with the leader interviewed to clarify any points that were unclear and to allow the leader to gauge the accuracy of the account. I sent a copy of each interview transcript to the interviewee and asked them to make any changes or corrections they wanted.

Thick description. Creswell (2003) recommends the use of thick description to convey findings. "This may transport readers to the setting and give the discussion an element of shared experiences," (p. 196). Because these case studies seek to capture the insider perspective, scientists/founders' "own words were used to construct 'thick descriptions' of their experience" (Sapienza, 2005, p. 474).

Audit trails .I kept a reflective journal that provided detailed descriptions of the occurrences, procedures used and any situations that arose for the duration of the research. I also kept all records, recordings and files locked, or stored in a fingerprint protected laptop computer.

Limitations of the Study

There are a number of limitations of this study. Qualitative research is, by nature, subject to interpretation and perceptions of the researcher. My presence during the one-on-one

interviews impacted the conversation. The leaders and organizations chosen were picked partially by the leaders comfort and willingness to participate. Because this research is a multi-case study, the study is not generalizable to other leaders and organizations, but may provide transferable data and concepts.

Another challenge was the openness and willingness of those being interviewed to provide candid, subjective responses. I was only able to interview each participant for one, one-hour interview and the data collected are reliable only for that point in time. To encourage participation, I provided the transcript of the interview for validity and reliability to each person interviewed and asked them to make any changes or comments they felt would help clarify their statements.

Ethics

This research conforms to the standards set by Antioch University and was approved by the Antioch University, PhD in Leadership and Change, Internal Review Board (IRB) before any research began. I completed an online course in ethical research and I also participate on an IRB with a non-profit biologics research organization, so I am familiar with the processes, expectations and ethical considerations when researching human subjects. I obtained a signed "legally effective informed consent" form from the subjects. (See Appendix C for Informed Consent Form). The form provided an explanation of the research project, what is expected of the subject and any foreseeable risks and benefits to the subject. I explained that participation is entirely voluntary. I provided a human rights statement that included the contact information of the current Antioch University Professor responsible for review and approval of IRBs. I explained the consequences if the subject decides to terminate their participation in the project and I provided "a statement that significant new findings developed during the course of the

research, which may relate to the subject's willingness to continue participation," (Antioch University Informed Consent Form, 2004).

Chapter IV: Results

Introduction

The following are three case studies based on interviews with senior managers at biopharmaceutical organizations with scientist/founder leaders. The companies all have products being tested in human clinical trials and one company has commercialized products, revenues and profits. I interviewed the chief executive officers (CEO) from each organization and their senior executives. The CEO from Company A also allowed me to use aggregated, anonymous quotes regarding leadership from a 360 degree assessment he had recently undergone. Background information and major themes are presented for each case.

In addition, I also interviewed three industry professionals who are experienced in management issues facing scientist/founder leaders at biopharmaceutical organizations. One is a venture capitalist, one is an executive coach and the third is, himself, a scientist/founder leader and a consultant to investment bankers. I spoke with a total of 17 individuals face-to-face and three interviews were done by telephone. I used the interview template described in the previous chapter. The interviews lasted for 45 to 90 minutes each and were digitally recorded with permission from each interviewee. The interviews were professionally transcribed and then sent electronically to the interviewee for review. The interviewees were all asked to verify the transcription of their interview and to make any changes or revisions they felt warranted. Interviewees agreed to allow me to use the information and quotes for this dissertation. The interviewees also signed an informed consent form as described in the previous chapter.

Although many themes emerged from the interviews, the main, consistent theme was associated with transition and change within the organization. Each person interviewed described leaders of successful biopharmaceutical organizations as being able to adapt to changing

leadership needs of the organization as it has grown. The individual cases are presented below, followed by a section on responses from the industry consultants.

Company A, Growing Pains

Introduction

Company A is a biopharmaceutical company founded in 1999 with $3 million in venture capital funding. By 2001 the company had raised $70 million in private capital, one of the largest-ever financing deals for a U.S. biotechnology firm. For the first nine months of 2007, revenues were less than $1 million, and the overall net loss was more than $15 million. However, the company had more than $30 million in cash, cash equivalents, and marketable securities. The CEO and scientist/founder of Company A stated, “We are pleased with the progress we made this quarter in our clinical, pre-clinical, and collaboration programs. Our lead candidate continues to progress through Phase I and II clinical trials, and our collaborations continue to go well." Company A is considered a successful biopharmaceutical company even before it has products on the market. This success is based on revenues that come from investors and partnerships with other organizations and the company’s rich pipeline of products in development.

The company focuses on the discovery, development, and commercialization of therapeutic drugs. The company’s initial public offering was in 2005, and its growth strategy involves pursuing partnerships with other pharmaceutical organizations. There are currently 60 employees and its lead drug candidate is in phase II clinical trials. The CEO stated, “The challenge is there is only so much you can do with 60 people and our budget. So what is the alternative? We have the opportunity to build much more value in the next few years [by partnering with pharmaceutical companies].”

Company A is in a transition period and is experiencing growing pains as it transitions from a science-focused organization to a patient and product-focus. Of the 60 employees, approximately 20 are in business and 40 are scientists. As it transitions from a science-focused company to one focused on the clinic and patients, the styles of leadership that have worked well in the past are not working as well with newer executives. Several executives were hired over the past few years to develop the company's first drug products. The CEO's natural style is collaborative and consensus building, but as the data will show, this is not always the best style for a company with products leaving the lab and moving into patients. According to the CEO, "Being the collaborative and inclusive person that I was, as my management team started to develop, I would defer in many cases to their abilities and expertise without as much discrimination as I should have."

Biographies of interviewees. The CEO is a co-founder of Company A and has served as President and CEO since the company's inception in 1999. Prior to founding the company, he was Senior Scientist and Group Leader at a large biotechnology company. He currently serves on the Board of Directors for national and regional associations for biotechnology. The CEO earned his doctorate degree in human genetics and cell biology and has published more than 50 scientific papers and holds several patents.

The Executive Vice President & Chief Business Officer joined the company in 2006 and is responsible for developing new commercial opportunities, directing all business development activities, and contributing to corporate strategy. Formerly, he served as the President and Chief Executive Officer of a pharmaceutical organization. Prior to that, he was the President and Chief Operating Officer at a therapeutics organization and the Senior Vice President of Business Operations at another biopharmaceutical company. Prior to this, he worked more than 15 years

with a major pharmaceutical company. He holds a master's in business administration degree in finance and in pharmaceutical marketing.

The Executive Vice President and Chief Financial Officer was previously with a major biotechnology supply company where he served as Senior Vice President and Chief Financial Officer. Prior to that he was the Chief Financial Officer, Secretary and Treasurer, Corporate Controller, Accounting Manager, and Budget Manager at other life sciences companies. He has a master's of business administration degree.

The Chief Medical Officer joined the company in 2006 and is responsible for all clinical, medical, regulatory affairs and serves as the key contact with the USFDA. Prior to working for Company A he served as Group Director of Oncology for a major drug Company And he was a senior administrator at the National Cancer Institute. He holds a medical degree and is a board-certified oncologist.

The Senior Vice President, Product & Pharmaceutical Development joined the company in 2002 as a Senior Scientific Director and has served as Senior Vice President of Product and Pharmaceutical Development since 2006. Prior to joining the company, he worked at a major drug Company As a principal scientist. He holds a doctorate in molecular and cell biology.

The General Counsel & Senior Vice President of Operations is a co-founder of Company A. Prior to joining Company A, he served a government attorney. He holds a juris doctorate and a master's of business administration degree.

The Vice President of Research joined the company 2000 and became Vice President of Research in August 2007. Prior to joining Company A, he was an academic professor. He holds a doctorate in biology.

The Senior Director of Human Resources has worked for Company A since 2001. Prior to 2001, she was Director of Human Resources for several organizations and a private consultant. She holds a master's of science degree.

Researcher experience. I met the CEO of Company A briefly at several biotechnology association meetings between 2005 and 2007. We did not know each other well but were acquaintances. In August, 2007, I again saw the CEO at a meeting and approached him about the idea of my dissertation research. He was very agreeable and I told him I would contact him with more information after my dissertation proposal was approved. I contacted him by e-mail in early October and he agreed to a one-hour face-to-face interview in his office.

Company A is located in a suburban industrial park situated near a major highway. As I entered the modern, brick, three-story building, I immediately noticed in the lobby a large glass wall separating a well-equipped research laboratory. It felt as if the laboratory was actually sitting in the reception area of the company. I thought to myself: clearly, this organization has a strong science focus. While I waited for the CEO's administrative assistant, I noticed a large display case with glass shelves that showed off various awards, both for the Company and employees. The administrative assistant soon appeared and escorted me to the CEO's office. The office was moderately large, with an executive desk at one end and a small conference table at the other. It was pleasantly appointed with professional furniture.

The CEO greeted me with a handshake and friendly smile and we sat at the table. As I began to explain my research, we were interrupted by the administrative assistant explaining that the CEO had an important call. I was allowed to stay in the office while the CEO talked on the phone for about 5 minutes. We began again, but he was again interrupted by a phone call. With each interruption, the CEO apologized and said that once he worked through the issues from the

phone call, he would make sure we were not interrupted again. The CEO and I talked for almost an hour and a half. He was surprisingly candid and willing to share information about his leadership and the difficulties in running a start-up biopharmaceutical company. He freely admitted his challenges, but also was confident in his ability to successfully lead the organization. He also told me that he had recently had a 360 degree assessment done and would be willing to let me read through the results. “A 360 degree assessment gathers information from several people about an individual’s performance as seen by their boss, self, peers and direct reports” (TotalPerformance360™, 2008). We agreed that if there was any part I wanted to use in the dissertation, I would tell him what part I wanted to use and he could decide whether I could use it. I came back some weeks later and reviewed the analysis and requested that I be allowed to use the open-ended comments as quotes in my dissertation. He agreed to this and part of the data described below will be anonymous quotes from employees from throughout the organization. This document will be referred to as A9.

After my interview with the CEO, the CEO sent an e-mail to all his senior executives asking them to allow me to interview them. They were given a choice, but it was clear that the CEO expected everyone to participate. Within two days of the e-mail from the CEO, every company executive had contacted me either direct by e-mail or through their administrative assistant to schedule an interview.

The first interview after the CEO came two days later with the Director of Human Resources. She was the only woman at the company I spoke with and is technically not an executive. She was, however, the highest-ranking woman in the company. When I arrived at the company, she was called and personally came to the front to escort me to her office. Her office is located down a long hall from the CEO and was situated between the science side of the

Company and the business side. This location seemed to reflect her status within the company, that of someone who works both with the scientists and business people. Her office was smaller than the CEO's but similarly appointed with a large desk and a smaller table at the other end. She had a large jar of candy on her desk, and she offered me candy. She said that she uses the candy as a lure to attract company employees to feel comfortable coming in her office. She stated that frequently, people will stop by for a treat and then end up talking with her and sharing their concerns or news from throughout the company.

Two days after my interview with the Director of Human Resources, I came back to the company to interview the Chief Financial Officer (CFO). I was escorted to a small, plain conference room that held a large blonde wood conference table. I had waited about five minutes when I realized I did not have a copy of the Informed Consent document. I walked around the corner to the receptionist and asked her to make the copy for me. I was away less than two minutes and when I returned the office was still empty. After another five-minute wait, the secretary came and said that the CFO had come, but seeing the office empty went back to his office to answer e-mail. She said he would come very soon. I waited for another five to ten minutes when he appeared. I wondered as I waited if there was any hidden meaning in my being kept waiting. Was this a show of power? When the CFO finally came he greeted me formally and appeared nervous and suspicious. He asked me many questions about my work and wanted to know if he was the only executive I would be interviewing. He wanted to be sure he was not identifiable. However, as we began to talk, he seemed to relax and was fairly talkative. Our interview lasted about 45 minutes.

I came back to the company two more times over the next ten days and interviewed five more executives. Each time, we met in the same small conference room. None of the other

executives kept me waiting. Some seemed a little suspicious as to why I was there, but all of them seemed to relax once we started talking. All of the interviews lasted from 45-60 minutes.

Key themes from interviews. I identified key themes from the interview with the CEO and then compared them with comments and themes derived from the interviews with the company's other senior executives. Some themes were unique to these senior executives, and these are identified separately.

A major theme that emerged early in the interview with the CEO and the executives was concern regarding decision making and issues stemming from the CEO being overly collaborative. This theme came up independently in every interview and in the anonymous statements from the CEO's 360 degree assessment. Another important theme that emerged regarded a level of conflict and frustration that has evolved from the CEO's perceived ineffectiveness at decision making. One person even mentioned that there was a power play happening among the senior executives as they jostle for position and favor with the CEO. Although other themes emerged, they were much less prominent.

The following themes emerged from the interviews and are listed in order of prevalence: decision making; leadership; conflict; change; success and failure; communication; culture; vision; goals; organization processes; and risk. The following sections include quotes from the interviewees as they relate to the themes. Some quotes are used in multiple themes. The speaker in each theme is identified by the letter A and numbers 1-9.

Decision Making

CEO and decision making. The CEO has an admittedly collaborative nature and has not always been as decisive as he feels he might be. This collaborative nature in decision making worked well when the company was smaller and more oriented toward the science. However, as

the company has grown, the CEO's decision-making skills have not evolved as quickly. He is viewed by many as being indecisive. The CEO acknowledges that he will need to adjust his style if he is to continue to lead the company toward success. "If I continue to be the CEO of the company, I will have to continue to grow appropriately." He noted that because he wants to be inclusive and collaborative, he has not always made difficult decisions quickly enough:

It was really obvious to everyone including me that a certain situation needed be moved in a certain direction or a certain person needed to be moved out of a leadership position. But because I was so busy being inclusive and collaborative, I did not make the hard decision. One way I have changed is that I am much more decisive by making hard decisions around personnel.

The CEO admits that his difficulty with decision making sometimes it creates "confusion and resentment in the organization at the senior level." Other senior executives discussed the CEO's decision making. One executive, A2 told the CEO that the decisions the CEO makes "in the next six to nine months will determine whether I want to stay here. [The CEO] is the boss so he gets the final decision. But sometimes, a decision for [the CEO] is putting off a decision.

Other executives are also frustrated by the CEO and his decision making process. A3 believes that the CEO is capable of learning to be more decisive and if he doesn't, then should step down. "If the board thinks that he hasn't made that decision fast enough, they probably would encourage him to step down. So there are some safeguards in there." A4 expressed his opinions more strongly. "[The CEO] by his own admission, is a person that, if he is not forced to make a decision, would prefer not to." However, he went on to say, "It's not just that he isn't comfortable making decisions. There are plenty that are made immediately."

A8 also brought up the CEO and decision making. "By [the CEO's] own admission, he doesn't like making decisions." A8 reflected that the CEO has grown with his decision-making

skills. “He used to be terrible at making a lot of decisions, but he has really grown a lot in making the big decisions; and he’s also willing to delegate decisions better than he ever did before.” The CEO may have difficulty making decisions because he wants everyone to like him. “With [the CEO], it’s more important that you like him.”

The CEO shared comments from a 360 degree analysis instrument used by his executive coach. The comments below are anonymous, but also reflect a concern about the CEO’s decision making ability:

> [The CEO] is reluctant to make the difficult decisions. He is tentative in the face of a vocal minority, and loses focus on the critical path because of it. He needs to either delegate decision making authority to others, or garner insight through his people and make the decision himself. Rather than asking people what they think about a pending decision, he should ask them what they see as the consequences of making a particular decision, were it made.

> [The CEO]’s emotions can get in the way when some actions or decisions need to be made. When his emotions get in the way, he has trouble making decisions or taking action.

The CEO needs to “be more decisive and demonstrate a clearer direction for the company. Delegate responsibility and accountability.”

> [The CEO]’s greatest leadership challenge is his ability to make timely decisions. Corporate/executive decisions at [Company A] seem to take longer than they should. I’m sure part of this is due to the number of decisions being made, as well as wanting to get it right. However, as the primary decision maker for any organization, I think it is important for every CEO to be able to make timely decisions.

> “[The CEO needs to] make more of the really tough decisions around personnel.”

Decision-making process. The CEO and his executives discussed the decision-making process at Company A. Originally, decisions were made by the executives reaching consensus. However, as the company has grown and there are more executives, the process has changed. The CEO stated “On the science side, we quit making major decisions with everybody sitting around the table arguing.” The CEO pointed out that some people in the organization felt left out

when the decisions no longer include them and according to the CEO, “there are people in the organization that feel every time we have a major scientific decision, we [should have] had an all hand session.” Many of the scientists have struggled with the business decisions that needed to be made. The CEO stated that even after decisions are made, some scientists don’t always agree with the decision. “Decision making can often times be robust and sometimes conflictual discussion.”

Some felt that it is easier to make decisions in a small organization. A2 noted “In a small organization you can make the wrong decision and figure it out and change it much easier than you can in a large organization. But at least, you start to move things when you make a decision. Of course, if you always keep making bad decisions, you’re just wasting a lot of resources, but, it’s important to be decisive.” Sometimes decisions are made by default. A2 described the decision process used to promote a director to a vice president position. “He has sort of functioning as a director, and, the company has been looking for his -- I guess, his boss for a number of months. And then, the decision was, you know what, “Let’s just let [him] run it.”

A3 spoke extensively about the frustration many have with the decision-making process. He said that, previously, decisions were made by consensus. However, this approach became too cumbersome for a large group of executives and the resulting change left some with hard feelings. He pointed out that the addition of new executives caused some of the former executives to feel left out of certain decisions and the new executives sometimes feel frustrated that they do not always have the autonomy they expect.

There are some new folks in the mix and I think they have different definitions of roles and responsibilities and the way decisions would be made, versus some of the older folks. There is a little bit of a challenge at the senior level of how we resolve that. I think the older folks are

used to a very small group where everybody would kind of get together and they'll all discuss it, and then actually it wasn't really clear whose responsibility an issue was. It was sort of consensus, and a lot of people would have sort of veto power. In some cases, it wasn't clear who could actually make the decision and run with something, versus who could veto it. Some of the newer folks come in and are more hierarchical oriented, and they say, 'This is my area so it's my call. I'm happy to have your input, but at the end of the day, I decide.' In the leadership ranks, there's either been some confusion or a little bit of testiness around that at times. But I think as for the guy at the top of any organization, that person has to set the roles and responsibilities and the culture of how decisions are made. I would say that's kind of an issue here. I think it started out with a very small entrepreneurial group and a lot of consensus. It's hard to move away from that as we grow bigger.

A3 also described frustration with the consensus style of decision making. "You need a decision today, but you can't reach three or four people; you have to track them down. Whereas the new guys are more along the lines of well, let's just go do it. This is my decision." A3 added that it is not always clear who makes the decision and stated that sometimes decisions are reversed. "You will think that something has been decided at some point, and then somebody else will come around and raise an issue with the CEO and the decision will be changed. So, there is kind of some bouncing around sometimes. You get that in all organizations, but maybe there's a little more here than at other places."

A3 further described the level of frustration as involving many people at different levels in the company. "I think there's been a level of frustration throughout the ranks. As you talk to different folks, I think most of them will be frustrated, but in a different way. Some people will be frustrated in that [they] thought we made that decision and now all of the sudden I'm finding

out that it's something different. Some people will be frustrated by [why] I wasn't included in the first decision, so my voice wasn't heard." A4 also described feeling frustrated with the results of the decision-making process. "There are certain times when I completely disagree with what's been proposed and look to [the CEO] or somebody else to say, 'Yeah, I think [name deleted] is right.'"

A5 concurred that the decision-making process needed to change. "The decision-making processes that we used in the early days worked then in that context, in that organization. They would not work in a bigger organization. And as we look forward they certainly will not work if we were to increase in size and double." He said that decision by consensus worked in a small group "because it allows you to get buy in. It allows you to get opinions and make sure you're not making mistakes." He said that decision making by consensus stopped working as the company size approached 20 employees.

> When you get to 20 people and not everybody's doing everything and not everybody's aware of everything, what winds up happening is that slows down the decision-making process to such an extent that you become hide bound or it takes too long to get the decision made because you have different departments now, different functions, different factions, you have different opinions, and you have to kind of negotiate and reconcile with each one and it does not work.

A5 described consensus making as too slow, and he felt that the company needed a better decision-making process. "The counter side to the need for process is the need for speed. There's a dynamic tension between how much time you spend on getting tasks done and how much time you spend discussing and deciding how the task should be done."

Many executives expressed frustration with the decision making process and complained about the difficulty and tensions that have resulted. A8 said "There are some decision-making authority issues going on." He went on to describe a tension between some senior executives surrounding decision making. A5 also discussed the difficulty with the decision-making process

as the company has grown and new executives have been brought in. “When you got a new set of personalities, you wind up not having the procedures for how finance is supposed to relate to marketing or legal, whatever. And so each one of those becomes a negotiation until you kind of get a feel for what the touch points are.” A7 expressed a similar perspective. “There is the managing of the personalities, which is much more of an organizational management; there is the managing of the science, which is much more of an expert domain. The people that are experts get to make the decisions.”

Decision making and leadership traits for company success. Two senior executives discussed decision making and leadership traits that are important for company success. When asked what the company needed to continue its success, A2 responded,

> Why -- I think decisiveness. I don’t think you can run a large organization – by treating everyone equally, not every function is equal in an organization. And there are some functions that are more important than others. What is critically important for an organization? And resources should be applied to those. It’s not as if -- resource should be distributed equally just because we want to stay equal.

A5 said that the ability to adapt and change is critical to success. As the company grows, the CEO will need to shift from focusing on science to becoming “much more of an ambassador both of the board and to the investors.” A5 also described the early stages of the Company As having a very “collaborative decision-making process in which on almost any significant decision, we would pull most if not all the key staff people, get their opinions, explain why we were planning to do what we were planning to do and then make a decision, and then [the CEO] would lead that process typically.” A5 said the company is at an inflection point. “Where what you’re doing no longer works and you need to change your style of management.”

Leadership

Role of the leader. Many executives discussed their perspective on the role of the leader. They described the leadership role as someone who is the "synthesizer and the driver towards the vision," (A1) and one who has "the ability to select and motivate the right people" (A3). Additional leadership roles include communicating well (A3), experience, "the ability to get the job done," (A3) and the "ability to learn and ability to change and adapt" (A6). A3 explained that "Part of our communication is just getting people excited about their jobs." A8 stated, "I'd say a high level and careful scientific exploration and principles, perseverance, because when you really have a rough time you have to persevere. And then a leadership that drives both of those and keeps them going in a way that can bring a product [to market] eventually."

Visible leader. Two of the executives expressed concern that as the company grows, the leader may not be as visible to the organization because his duties and responsibilities will bring him outside the company. A4 mentioned that currently the CEO "tends to walk the length of the building. So there is that sort of stirring effect." A4 said he believes in "management by walking around. To me, it's important to keep just sort of seeing people and faces and recognizing that they're humans. They aren't just a name on an org chart." A8 expressed concern about the leader's ability to be seen throughout the organization as the company grows. "The leader sets the culture. As long as he does that, you'll probably keep people admiring that and wanting to strive for that and work for him. If we get bigger and he can't be going out so much and gets less visible, and travels a lot, you know, things permeate."

Gender issues. There was only one female interviewed and in fact, she is not a senior executive, but a director. Her number will not be identified, but she is the only person who discussed gender as a leadership issues. She stated, "One, I don't like that we don't have enough

female people in leadership positions. It just drives me nuts. I am the lone person in the wind, and I am a fairly typical female leader. I am not confrontational. I don't like a lot of things that go with it." In fact, all of the leaders at Company A are white men.

Leadership traits. Many of the executives, including the CEO, interviewed described leadership traits of the CEO. The CEO used the words collaborative and inclusive to describe himself many times during the interview. These traits are evident in his use of the 360 degree assessment tool that he commissioned to gain more information about himself. He even allowed me to use the open-ended statements of his employees who had completed the instrument. The CEO feels that his collaborative nature and his ability to "see a relatively clear vision and at the same time, be able to articulate and get buy in from various stakeholders and constituencies is one thing that I think has both seen [Company A] through some very difficult times in the biotech world and some ups and downs in the last eight years in which many companies that were in our generation went out of business." Another example of the CEO's inclusive nature is his ability to work well with his board of directors. "I was able to sit with all of those venture capitalist that were in my board room one by one and make them feel they are the part of very inclusive team which had total transparency to the management."

The CEO has been extensively interviewed in trade journals as a young, successful entrepreneur. He described his views about leadership traits that can lead to failure in one interview (citation omitted to protect identity of CEO). "Egomania is a destructive trait. Thinking that you are smarter than everybody else only means that you aren't. Thinking that your idea and way of doing things is always the best and should be adjusted only in the most dire circumstance is the kiss of death for any company sooner or later."

The senior executives described the CEO as “honest” and “non-confrontational” (A2). A3 agrees that employees see the leader as honest and said “Other leadership attributes are sort of getting people excited and jazzed up, you know, empowering the heart.” A8 describes the CEO as a “modest man” interested “in doing the right thing, the right way.” A8 also said that the CEO admits failings and that “makes you want to help fill in those bits and pieces. Those are the characteristics that make you want to follow him.”

The CEO allowed me to read and copy the open-ended statements in the 360 assessment regarding his leadership assets and challenges. Respondents were asked what the CEO’s greatest leadership asset, skill, or talent was. Words used to describe the CEO did not vary much from the comments made by the senior executives. Humility, ability to seek and receive feedback, ability to communicate the vision both internally and externally, ability to inspire people to work hard, “he is trusted,” and “putting people first with praise,” were statements used to describe the CEO. When asked what the greatest leadership challenge or area for development they would suggest for the CEO the same respondents also mentioned traits that the executives used. The most common trait mentioned was the leader’s decision-making ability. Others said he is “emotional” and “overly optimistic.”

Conflict

Although conflict and frustration came up in the section on Decision Making, those quotes will not be listed again here. This section will deal with other forms of conflict, tension, and frustration including conflict between scientists and business people, organization conflict, power and difficult people.

Science and business conflict. Tensions exist in Company A between scientists and business people in part because it still retains a strong science focus. A2 asked, “How do we take

this science - this cutting-edge science - and turn it into something that is able to generate a return and provides benefits to patients? And, that's some of the basic conflict between sales and research." A3 feels that part of this tension results from many of the scientists having a strong academic focus with little company experience. "Given that many of the people here came out of academia and haven't had that kind of company operating experience, sometimes those issues come in conflict." Scientists may be more used to uncertainty and the need for change because of their background in research where uncertainty is a given. A7 feels that business people may simply not be used to things changing as much as scientists.

I think the business side is much more interested and comfortable with laying out a plan and just following the plan, and letting it go. Whereas the scientist, by necessity, even if you lay out a plan you know it's going to change. Every time you come to a new piece of data, you evaluate change. That is good because for that function you need to evaluate every point and change to the correct path, but it can drive the business people crazy. And the business people can drive the scientists crazy because they're unwilling to change sometimes.

A7 acknowledged that business people need to predict what will happen. "On the business side, it's best to have predictability. On the science side, you can't predict that my clinical trial is going to work or not work. I can't even give you a percentage of what it's going to be, and I can't tell you whether it's going to take six months or a year. It just depends, and you can't say that on the business side." A7 added that this difference between scientists and business people is a large source of conflict between the two. A7 understands that there has to be for milestones and goals, but this "actually makes [scientists] uncomfortable." When describing himself, A7 said, "I think it's very difficult for a scientist to make that kind of organizational leap because not only are you not trained to do it, but you're actually trained to do almost the

opposite: Internalize a lot of things and work them out yourself. That's the one advantage I have on that side and the business side. I actually like it, so it isn't a necessary evil; it's just a necessity."

Part of the scientific process requires that scientists continue to work on a project until they have answered the questions they pose when doing the research. This process does not always work in a business environment because projects often need to end by a certain date or there are milestone that need to be met regardless of whether enough information has been obtained. This limitation may result in projects being discontinued if they cannot be resolved in a timely manner. A7 stated that

> When do you quit something that isn't successful today? The scientist always says, "Well, I'll run another experiment and it might work this time," or "I have a new idea and I can try this new thing." And the business person says, "Well, you know, three strikes and you're out."

A7 described the transition he had made from science to business. He said that it was particularly difficult to not have the luxury of being able to think about decisions and ideas as long as he would like. "That's difficult to do for a scientist who wants to read papers, think about it, and have a two-hour conversation about it. I think that's the big transition I have to go through. I have to let go of the operational taking care of things. Part of it is trust and part of its kind of obsessive-compulsive scientist person."

According to A8, scientists in Company A may have disagreements, but they quickly are resolved without hard feelings. A8 feels that the business executives are more competitive and less likely to get along. A8 stated that the scientists, "by and large do like each other. The business side is really more defined by a sense of competition among the executives." A8 added that "I don't really see a lot of collaboration trying to work it out necessarily down there" on the business side.

A8 noted that people tend to prefer to talk about negative things, but when the CEO is around they tend to not focus as much on negative issues. “People are more comfortable saying and being part of negative things than positive things. The majority of humans like to tell you what’s bad. If [the CEO’s] around, you can’t really do it much.”

Organization conflict. As the organization changes to become more business focused, some interviewees felt conflicts would be inevitable. A5 stated that the tension “plays out mostly at the level of the executives. You can’t let the anxiety of running a business percolate all the way down to the rest of the organization.” However, A3 pointed out that if an organization is not ready for change, then there [are] probably going to be conflicts.” These conflicts may extend beyond the executives in science and business. A3 noticed that at the “lower level there are turf battles or issues.” A3 lamented that because people want to maintain the status quo and are resistant to change, some lower level people may not even realize that the change may result in an increase in their stature or position within the organization. “What I’ve encountered is that the lower level people rarely want you to give them anything new because they don’t want more work, which is reasonable, but they don’t want you to take anything away from them either, because if you have a task, there is a certain amount of status or something that goes with that; so if something is taken away from you, it looks like you’re not competent or somebody else is trusted more.” This resistance to change results in “people acting negatively, because they would feel that what they gave up was more in terms of status than what they got or they would be questioning why, so to me that makes it difficult to make changes in even things that are kind of small changes at the lower levels” (A3).

Even though there is conflict within the organization, some feel still prefer to work for a smaller organization. A4 pointed out that in large organizations it is extremely hard to effect change because an idea "goes to one layer of review and another layer of review."

Power

Several of the executives discussed conflict and power among the senior executives. A8 said that "of all the senior executives only the VP of R&D does not have the power play issue." Most executives in Company A work in the business area. Several people interviewed commented that there is conflict within the business area. A8 worries "this could end up as a company like a lot of companies where power and politics dominate." A3 stated, "Some people are trying to expand and some people [are] holding on to their positions. I think there are actually some silly little turf wars." A4 disagreed and feels "I don't think that this interaction that I have with one of the other executives is a power play. But I don't see it really happening amongst groups, you know, fighting for resources. At this point, we are still working for a common purpose." A8 feels that power struggles may be inevitable as the company becomes more business focused. "I struggle with seeing the power struggles down there [on the business-side], but you can't grow a company if you don't have that kind of aggression." This power struggle appears to have permeated the support staff and some support staff appear to be territorial. "There tends to be less of a sense of cohesiveness and more of a sense of territorial things in the support staff."

Two of the executives described difficulty with one particular person. A4 said, "I mean, we just see pretty much in opposite directions. I think he feels the need to tell me what my job is – not [the CEO] but this other person." A4 also struggles with a feeling of lack of support at times from the CEO. "There are certain times when I completely disagree with what's been

proposed and look to [the CEO] or somebody else to say, 'Yeah, I think [name deleted] is right.'"

A8 also described times when one specific person was especially difficult to deal with. "I don't need to relate to somebody who's been rude to me. I need to be professional. We have [name deleted] and on a personal level hardly anyone likes him, and on a professional level he's very difficult to deal with. You just don't get deals if you don't have those kinds of characteristics." There does not appear to be any mechanism in place for dealing with difficult people. A1 feels that "if you can frame things as clearly as possible in business terms, it goes a very long way toward resolution of tactical disagreements." A3 thinks that the way to avoid conflict is to not "overplay it and then just alienate everybody. Then it will never go anywhere. You've got to be smarter about the way you do it." Unfortunately, A3 did not describe how to "be smarter" in difficult situations.

Change

Change is inevitable in a biopharmaceutical organization if it is to be successful. Particularly in companies headed by a scientist/founder, there will be a transition from an early-stage science focus to that of a business focus. A6 stated that the "critical factor that I would define as absolutely essential is an ability to change and adapt." As discussed previously, the CEO has worked hard to become a more decisive leader from his collaborative style that worked well when the company was small. "One way I have changed is that I am much more decisive by taking hard decision around personnel, decisions at the senior level for whatever reason [were] not getting made as decisively." A2 hopes the CEO can change. "We're sort of at that crossroads in terms of whether [the CEO] is going to be able to, change, in order to make [success] happen. I would hope that he has the ability to change." If the CEO cannot change then this executive

predicts there may have to be changes at the top. “That is also a part of the cultural change that, a company from a startup biotech to a commercial entity, that is -- the cultural change is something that’s got to be driven by the CEO. And if that can’t be done -- or in that process, there may have to be changes of people.”

A2 sees himself as an “agent of change” in an organization where change is not always received well. Newer executive hires to the organization have brought different ideas and way of doing things and this has sometimes resulted in tensions among the group. According to A3, when he brought an idea for change to a different department, “there was a lot of resistance because of getting into somebody else’s area and suggesting things we ought to do there. I would have thought maybe the person would have said, ’Hey, this is great. Now I finally have somebody who is pushing this thing.' But that wasn’t the reaction. I didn’t know whether [name deleted] had never been through the process and totally understood it, or just thought it wouldn’t apply here, but there’s a lot of resistance.”

Change is hard for many people even when they know it is inevitable and the reason for change is good. A7 discussed the inevitable change that comes with company growth and a transition from being a science-focused company to a business-focused company. “I think when we go to the next level, then perhaps this whole senior group has to make that transition too. They really have to become more of the business people running the company. A7 described a transition point within the Company As it grew from 30 to 60 people. “Before that, if you had an issue, you walked next door and talked to the person who did it. There weren’t that many layers. Then when you get to this 30 to 60 to 80 people, there are groups and they’re operationally quite small usually, you know, five or six people.”

The transition from scientist to a business focus is difficult for some, but not others. A7 mentioned that he knew in college that even as he studied science he also was interested in business. “I think I didn’t have a hard time transitioning to those new things [science to business] just because of what I liked to do before. In fact, I think I had a harder time in academics being that isolated person. So for me, it hasn’t been that hard of a transition at all.” A7 has noticed the transition with the CEO. The CEO “is actually separated from the operational part of the Company A and has become more of the CEO. He’s lost some of his operational scientist person, which he had to. That was the only way he would have stayed, actually.”

Because the growth in the company has been slow for the past few years (as the result of a partnership opportunity that fell through), some feel they were given time to adjust to the coming changes. “We didn’t have that transition from 30 people to 120 people in a year-and-a-half, like a lot of companies do. It kind of allowed us to catch up to what the challenges will be, and to bring in some different people along the way, either that had been in those organizations or had seen that transition to kind of warn us” (A7).

Some in the company have prepared for the change to a more business-focus, while others have not thought it was necessary. A7 “read books about the transition and taken some classes, which have helped with varying success.” The CEO has attempted to bring more of a team spirit to the executives, through training classes, but according to A8, “I don’t see any change or learning going on. I think that’s because these executives don’t like that kind of stuff. They kind of pooh-pooh that kind of stuff. They go and pay homage to the class because [the CEO] says you’re going, but they walk out and just do the same thing. There’s no behavioral change really.”

One thing is certain, the executives all want change to happen quickly. “All of us are trying to modify our behavior; we tend to get our change over with quickly” (A8). “What do I struggle with? It’s probably getting folks to change as fast as I want them to change” (A3). And according to A2, Company A “is not changing nearly as fast enough as I would like it to.” The rest of the company may be waiting to see what happens. A2 stated,

> There’s probably 10, 15 percent of the population that is very change-ready. There is probably the same number of 10 or 15 percent as very change-resistant. And the balance, the people in the middle, the 70 percent of the people that are kind of figuring out who is going to win here. And then, they will decide which, team they are on. And I think some of that is taking place here.

A6 effectively summarizes the general view on change and Company A. “If you’re not willing to change the way you do things, it’s probably not going to work very long.”

Success and Failure

Greater good. Almost all executives interviewed indicated a focus toward the greater good of humanity. When I gave the definition of success as creating value within an organization, many said their view was different. A4 commented, “To me success is to develop a better treatment for cancer, not to create monetary value for the company, although clearly that’s a necessary component for a component to survive.” A8 claimed that Company A is humanity-focused “and it is worthy of great success.” Even if they eventually fail as a company, if their science proves successful, A5 believes that constitutes a success.

> If [the science] really does work it’s really paradigm changing. Even if that was the last money that we raised and we go down to fumes, to the extent somebody discovers a drug the way we’ve started to discover drugs and they say, those guys at [Company A] were before their time, as a scientist, and sort of a creator and innovator, we succeeded.

A5 noted that some may come to a biopharmaceutical organization because “In academia, you have very altruistic ideas that the research that you’re doing is actually going to

help somebody someday and, and you kind of realize after a while that, you're just writing a lot of grants."

A4 describes the Company As working toward a common goal. "I think it's both part of the success that people feel they are working with others towards a common purpose, because they see everybody else as their colleagues." Even those who see the company with a strictly business focus acknowledged that "you wouldn't launch a product that didn't provide patient benefit. As soon as the product starts going into humans, you have to start preparing for potential success - commercial - and success meaning an approval and commercial launch" (A2).

How to succeed. Almost all executives had suggestions as to how the company will continue to succeed. They mentioned learning, being adaptable, having a strong science vision, having successful partnerships, planning for inevitable failures, perseverance, and good leadership as all being necessary for success. In an outside, published interview, the CEO advised, "Seek out and listen to advice from experienced and successful entrepreneurs. Listen and learn from your employees. Listen and learn from your competitors; and be flexible enough to incorporate what you learn" (Anonymous, 2003). A6 stressed the importance of the ability to "change, ability to learn and ability to change and adapt" (A6). A7 agreed, adding that successful companies "plan for the failures that invariably happen and you have to build in flexibility, either in redundancy or in the ability to change to a successful program." A3 felt that to attain success a "strong vision of how the science can lead to drugs" is critical. A4 felt strong partnerships that can continue to offer payments on the chance that the product will be profitable is important. "Having developed partnerships that are going to bring revenue when you're 150 people, and have you coming closer and closer to profitability -- not necessarily on something that you sell yourself but on the fact that somebody you work with is selling something and

they're giving you a lot of that money" (A4). A8 felt that "a combination of the science and perseverance. I'd say a high level and careful scientific exploration and principles, perseverance because when you really have a rough time you have to persevere. And then a leadership that drives both of those and keeps them going in a way that can bring a product eventually."

Is company a going to be successful? One executive expressed concern that the company may not be able to continue its former success with the senior executive team currently in place. According to A2,

> I have made the statement to [the CEO] that it is my belief that the senior management team that is in place now will not, if the company will be successful, be the same senior management team in the next, two or three years. So that was my Draconian forecast. I know in order to be successful, I don't think the same team should be in place.

A2 went on to describe his extensive experience in the successful launch of several products. "I think I have a pretty successful track record of successes as you've defined it." He indicated that he would or should be part of the executive team that could make the company successful. A4 believes the company will be successful and said "I have a lot of confidence that [Company A] will be successful because I think we see a path forward." He did, however, express some doubt, and when talking about this research project he stated, "Your whole study is based on the premise that we will be a success, but it'd be nice to know that two years from now and five years from now [Company A] will be here."

Reasons for failure. Many of the executives offered advice regarding reasons many biotechnology companies fail. These reasons include intellectual arrogance, unrealistic valuation expectations, inappropriate skill sets, and not being prepared for change. In an outside interview, the CEO stated, "Thinking that you are smarter than everybody else only means that you aren't. Thinking that your idea and way of doing things is always the best and should be adjusted only in the most dire circumstance is the kiss of death for any company sooner or later" (Anonymous,

2003). This arrogance can also lead to unrealistic expectations of the value of the company or product. The CEO stated that "When entrepreneurs cannot accept the reality of the market for their idea, patent, company or services, they end up with nothing. Whether it's start-up companies seeking capital or later-stage companies trying to make deals, it's better to have a small piece of a big pie than a big piece of nothing." A2 and A4 felt that companies with scientist founders fail because many scientists may lack of necessary skills to successfully run an organization. A2 stated, "Why do a lot of biotechs fail? A biotech company may be started by a founder [who may not possess] the skill set that is required to start a company is not the skill set or them which takes it to the next level. If you are not change-ready or not prepared for change, there [are] probably going to be conflicts." A4 added, "I think a lot of businesses fail, especially when a scientist from a university or the government or has gone out to start a business; all the technology is there or at least envisioned, but how to put it into practical application often is not. Scientists often aren't great businessmen."

Personal failings. When I asked the CEO to describe a time when he failed, he mentioned his lack of decision-making ability. He gave an example of not moving someone out of the company when it was clear to others that the person needed to leave. "I'd say I am not firing people fast enough, intervening in a meaningful growth path for the person." The CEO gave another example of when he hired more employees because he expected the company to engage in an important partnership. "I did not get that partnership and so I had to lay people off." Interestingly, the CEO admits his failings to others within Company A. A8 said the CEO "admits to failings. Like all of us, he has deficiencies in certain areas. He's willing to say that about himself. You don't find that very often in leaders."

Failure and strategies. Two executives talked about failure as being inevitable, and they discussed how to respond to failure. A7 said that successful companies "plan for the failures that invariably happen. And failure doesn't mean that it's terrible and awful; it just means that it didn't get to the deadline on time." A3 said that some employees are not able to adapt and change as the organization evolves. "That doesn't mean you take them out behind the woodpile and shoot 'em in the back of the head; it means that you counsel them in some positive way into whatever the next chapter of their life is."

Vision

The CEO has a clear vision of what Company A can be. During my interview with the CEO, he mentioned the vision of the company many times. One of the first things he said to me was "I envision my role as the leader of the organization as the person who is the synthesizer and the driver towards the vision toward value." The CEO described himself as a capable leader who is able "to see a relatively clear vision and at the same time be able to articulate and get buy-in from various stakeholders and constituencies." The CEO admitted that at times he struggles with "how to be able to articulate that vision in a convincing way."

A3's interpretation of the company vision is very science focused, whereas the CEO understands that the company needs to generate value from the science. "I think you've got to have a good vision of how the science can lead to drugs or solve some therapeutic issue or problem. I think you've got to have the scientific vision. I guess that's a critical part of a success. Leadership is a good vision, in this case a scientific vision." A5 stated that he thinks "a lot of people believe in the scientific vision and what we're doing there." Many in the company seem centered on the scientific aspect rather than whether the science can be successfully

developed and sold as a product. However, A5 stated "I clearly see what we need to do to make that next step to succeed in accomplishing our vision."

Although the science has not been fully developed, no one interviewed said they should stop the effort. "The vision of our founders and of our original investors was to do 'this' and we stuck to it. The scientist leader/founder says we have a vision. Just because it's taking us longer to get there, it's still working. That doesn't mean it's broken and that we should deviate from it. We should stick to it" (A5).

Goals

Most executives agreed that the company sets clearly defined goals and all are expected to meet them. The CEO stated, "We set yearly goals as an organization and we formally review those goals in all of the departments. I communicate a lot around those goals, and I pay a lot of attention to whether or not the things that we are tactically and practically doing articulate it. The meanings of those goals are written with a very clear business focus and that helps the scientists the way they start to learn frame their goals." A7 pointed out that sometimes scientists may be uncomfortable with the timeframes associated with the goals. "There are goals and there are milestones you're supposed to reach at a certain time. Sometimes it's earlier and sometimes it's later, and I think that makes putting the prototypical scientist into this framework uncomfortable." A8 explained that the goals for 2008 were underway during my interviews and explained how those goals would be communicated to the employees. "Right now, for example, we're doing our goals for 2008. We have the scientific directors putting a lot of those metrics together, but they do that in concert with the VP of research primarily. Then they will get together with the executives, but at that point it's a very strong draft and it's being socialized.

Those are collaborative professional meetings. We have a staff meeting once a month, and basically once a quarter he'll go through our goals."

The CEO said that he has tried to create a corporate culture in which, if the goals are adjusted during the year, people are able to adapt. "We try to create a culture where everybody understands that at some point during the year we [may] come back and say there is a major shift and here is the new goal associated with that major shift."

The goals are communicated to the employees through several channels including face-to-face meetings. The CEO said, "A lot of communication is at staff meetings and follow-up meetings with senior executives." In addition, employees were given clocks that had the corporate goals printed on them. Each year, the goals are updated and new hires are also given clocks with the goals. "Two years ago we gave everybody these clocks that had the goals of the year in them" (CEO).

A6 pointed out that the executives are charged with making sure their own groups understand the goals and the executives are expected to talk with people about these goals in person. "We make a pointed effort to get out and walk around the Company and talk to staffers. That's really an issue in our goals." According to A8, "We have a vision and we do have goals. They are posted all over. They're on the intranet. Everybody should know what they are. They are stretched goals. You could ask anybody in this company if we had a vision or corporate goals. The answer would be 'yes.' Whether they've memorized them or not is another thing."

However, A5 said that employees are not expected to worry about corporate goals, but to focus on their own job and let the executives do any worrying. "We tell you what the goals are, but you need to think about the job you're doing, because for us to reach those goals we need you to do your job. We don't need you to be distracted and worry about it." He did add though

that it is important for employees to hear how well the goals are being met. “They understand what the scientific goals are, and for them to hear the progress of the projects I think is a big help.”

A5 describes latitude in how goals are met among the senior executives. “It’s our culture that in our executive forums, you say this is the decision I’m taking and this is why, but there’s a pretty high threshold for when it has to be vetted and this decision be made versus I’m just letting you guys know.” A7 concurred saying, “There are occasions where, particularly around when we write goals for year, the people get the ability to say this should be a goal.” A8 summed up the overall corporate culture regarding goals, “They do value the level of a good product. That’s what the ultimate goal is: to be proud of what it is that comes out.”

Communication

When Company A was smaller, people communicated regularly and informally. They also met each other outside of work. As Company A has grown, communication has become more of an issue. Communication is mainly done at “staff meetings and follow up meetings with senior executives” (A1). A6 said,

> When we were small, we were much more inclined to kind of socialize and you knew everybody in the company. You knew their kids, their wives, their friends, and you wind up spending time with them at happy hours or whatever and you got to know them. As it gets bigger, what I’m finding is that the time pressure is such that it’s very hard to maintain that kind of hands-on contact.

However, according to the CEO there is still a great deal of “of cross- communication in the product research area which is approximately 70% of the organization. We have five departments [that] are mainly collaborative and cooperative, and communicative… all of which by necessity have to interact a lot compared to most organizations.”

Because some in the organization complained that senior management had "lost touch with what was going on," a task force on communication was created (A1). The CEO wrote mid-year goals for each of his direct reports that required "they had to, in two distinct ways, every month go move beyond their comfort zone to reach out to establish a more deep connection with the rank and file. That took on many different forms depending on who it was, but all of them were accountable to me for the rest of year on a monthly basis."

This 'forced' communication resulted in mixed opinions from the senior executives.

A2 stated,

> We want to shut down the emails on Fridays so people can communicate – I don't think it works like that -- if somebody is introverted, you can't force them all of a sudden to say, 'You know what, on Friday, now you are going to turn into an extrovert.'

Some executives make a specific effort to talk with support staff and others in the organization. A6 stated,

> We make a pointed effort to get out and walk around the Company and talk to staffers. That's really an issue in our goals. Maintaining that kind of contact takes conscious effort. It really is a challenge to maintain contact with the rank and file.

A8 said, "I will find a way to go into each of their offices at some point. I visit the support staff with some regularity. We talk all the time. He'll stop down here and I'll stop in his office." However, A8 will not stop by the office of those with whom there has been a "difficult history. His assistant has been personally offensive to me, so I keep it extremely professional. I don't need to relate to somebody who's been rude to me. I need to be professional."

A2 wondered if lack of communication is really the main issue facing the company. He asked, "Are we taking communication and using it as a scapegoat? Are we making this an issue - a bigger issue than it needs to be?" He believes the CEO has been "hijacked on this issue." A2 agrees that communication is very important, but he thinks that the CEO may be overreacting.

> I don't think [the CEO] needs to send an email attached to the press release after the press release had gone out saying, 'We had a press release.' To me, as a CEO, he certainly has more pressing issues to address; even though, that is a nice personal touch, but that doesn't help communicate. That does nothing other than they got a second email basically on the same issue. Communication is two-way.

A3 agrees that two-way communication is important and stated that he thinks it is important that the executives are available to answer questions and set the vision and deliverables. "It's their job to ask us what they don't understand or what they need to know. Part of our communication is just getting people excited about their jobs. And not only excited about their jobs, but they need to have confidence that the leaders know what they're doing and that they're worth following."

A2 wants to be certain that the results of the effort to increase communicate results in true communication. "Let's make sure we have a real open dialogue. Let's really understand the issues." He did not offer suggestions as to how to make true communication happen.

Culture

Transition to hierarchy. Company A began with five people. At that time, the culture was entrepreneurial and the there was no hierarchy. As Company A has grown, so has its organizational requirements and now there is a more hierarchical structure in place. The CEO noted that, "The culture that grew up out of the beginning was having everybody being more or less on the same level. No hierarchy. As we started to get bigger, I started noticing that non-hierarchical approach was going to need to change as the company grew." The transition to hierarchy resulted in some conflict and tensions that were discussed in the previous section on conflict. The original core group of executives wanted to keep the flat structure as long as possible. The head of HR stated,

They are more hierarchical, which was a very difficult adjustment. When I came here and interviewed they said, “How can you keep us the same as we grow?” I said that I couldn’t keep you the same. You don’t want to be the same. You don’t want to be flat-lined. You have to have hierarchy. You always have to have someone where the buck stops here. Some people have been very resistant, but it really is the right way to go.

A5 pointed out that it took time for the new hierarchy to be accepted. “It’s taken a while, for us to build that into our culture and it was also a matter of our management team really showing the rest of the company that as a management team we could -- when we went public, we did something nobody else did.”

Collegial culture. The executives described the culture at Company A as “respectful,” “pleasant,” “collegial or family-like” and “pretty much everybody gets along.” A3 noted that this family-like atmosphere makes it difficult when an employee needs to be let go because “it would be like asking your nephew not to be part of the family anymore.”

A8 described discussed the culture at Company A extensively. A8 said that there are two “subcultures” within the company, that of the business side and the other of scientists. As previously mentioned, scientists make up about 70 percent of the employees at Company A. A8 said that the scientists are “people who really want to get the job done; people who are willing to put in long hours; people who like each other and don’t tend to compete with each other. They see the greater good.” A8 described the business side of the Company As “a guarded competitive atmosphere” where there are tensions and frustrations among the employees. These were discussed in previous sections and will not be re-addressed here.

Another aspect of the culture at Company A is one of public recognition. Employees are given awards and prizes for work well done. Some think this is a good idea; others question

whether it can sometimes be “patronizing” (A8). The CEO seems proud of the way people are recognized at Company A. “We have cubes for promotions. They actually can have three lines on them so each time they get a promotion they can get up three lines.” The CEO also described the [Company A] Award for employees who are promoted. The CEO and other executives also “go about in staff meetings trying to see that people get recognized. We have a program called Invention of the Year program” that is similar to the Academy Awards. The CEO said that only once or twice has an employee refused to be publicly recognized. According to the CEO, one employee told him that receiving the award was one of “the two most important things in his life…meeting the Pope and working for [Company A]”.

Process

Need for processes. The executives discussed the need for more processes in place as the company grows and increases its visibility to the industry and to the USFDA. A6 stated that,

> A small company generally doesn’t get a lot of regulatory attention. But as you get bigger and more successful your visibility increases. So a much better awareness to the outside world and to change the processes inside the company to prepare us to deal in more robust way when we’re more visible and larger.

A6 explained that “You need to understand how you get a pill approved or how you make a decision, or who has to be consulted when you don’t want a contract out.” A3 agreed that more processes need to be in place, but he feels resistance to this idea. He stated that he is “not trying to bring in huge bureaucracy,” and that simplification is actually probably easier to do and maybe more important here than it is in a big place.”

Task versus process. Some executives described those who start up companies are generally more focused on task, rather than process. A6 stated, “The people who started as a startup still have more of an orientation on task and less orientation on process.” A 6 argues that “the counter side to the need for process is the need for speed.” Because there is a large amount

of work that needs to be done, time needs to be spent on the task at hand; however, processes need to be implemented to make sure there is consistency in the work." A6 said that "In a small company you don't have the level of resources that you typically would have in a larger company. You don't have folks who can really focus on process." He described a tension between how much time can be spent on doing a task versus how much time should be spent designing the process for doing the task. A4, agreed that "Time is an issue. To have enough time to get everything done."

Management training process needed. A3 described a need to have more training in place to help managers better understand the processes necessary. He stated that some managers are not good at certain processes, such as evaluating people, but could improve with the proper training. "Here, it's all very independent so each manager fills in their form and you don't know how your people stack up versus other people." Those that do not improve would be moved to different positions. "At a bigger organization, there's more infrastructure on training supervisors and bringing these skill sets up. That's going to be a critical component of our growth."

Risk

Several executives described the risk they took in coming to a start-up biotechnology company. A6 said "it would be nice to know that two years from now and five years from now [Company A] will be here." One executive described his previous job as being less risky and wondered, "what happens if the company falls on its face" (A4)? A6 described being surprised at the high level of risk.

> It was a decision for myself to leave a very secure job to go to this new thing. And the reality in a biotech company is if you don't make your milestones, if you don't show progress on the money you got, you're not going to be able to raise the next round of financing.

In addition to the risk of the company failing financially, there is also the risk involved with so few key personnel. If one of the key staff were to leave or be unavailable for work, the perceived value of the company could drop. A6 described a scenario where if "somebody is in a car accident and is in the hospital for six months and can't come to work, that can be devastating for a small company because every set of hands counts."

Company A mitigates some of this risk by developing some products that are more likely to succeed, but may not have as high a rate of return. A7 stated, "I think we kind of chose this path of doing some things that are predictable and some that are more high risk." He explained that Company A partners with other companies to bring in more revenues, while also doing some "high-risk things that have big value so that the investors want to invest in us."

Summary of Findings

Company A is transitioning from a research-focused company to one that is in the development stage. The change has caused the leader to have to grow and change his style and this has necessarily resulted in some difficulties in the organization. This case described the findings from interviews with 8 employees and aggregated data from a 360 degree assessment the CEO had recently undergone. Major themes that emerged include decision making, leadership, conflict, change, success and failure, vision, goals, communication, culture, process and, risk.

Company B, Sustained Success

Introduction

Company B is one of the relatively few true success stories in the biotechnology industry. Founded in the 1980s by a senior research biologist from a large established pharmaceutical corporation, the company has grown to become one of the top ten largest publicly traded

biotechnology companies in the United States with annual revenues of approximately $2 billion and more than 3,000 employees. The strength of the organization comes from its charismatic, possibly genius, leader and chief strategist. This leader, now the scientist Chief Executive Officer (CEO), was only in his early 30s and had no prior business experience when he founded the company. Early on, he brought together a team of young scientists who were groomed and experienced from their work at various pharmaceutical organizations to become the senior executive team. The CEO admits he is talented at picking the right people.

> I mostly pick guys who are smarter than me and more accomplished than I am. The same thing with my board; I built the board the same way. They know stuff I don't know. You want smarter and smarter people around you and guys who have done things you haven't done yet.

The company has managed to survive and ultimately thrive in an industry where the majority of promising biotechnology companies are bought by pharmaceutical organizations. This 'exit' is viewed by many as a success. How has the company managed to grow where so many fail? The answer appears largely due to the CEO and his team. There is no shortage of information and articles concerning the CEO and the company. From interviews with senior executives and the multitude of articles written about the CEO and the company, a picture of its success comes together. Clearly, the organization knows how to present a united, professional face. From the way I was treated during my time visiting the company to the image the company is viewed by the industry, it projects professionalism, experience and success.

The company's strategy for continued growth includes continued sales of its core products, new product launches, acquisitions, and industry collaborations. The company currently sells more than 30 pharmaceutical products and has at least nine products in development from the preclinical stage to phase III clinical trials. It has several locations in the United States and offices in more than 60 countries, with direct sales in 25 countries.

In the early 2000s the company sponsored internal research to determine the key ingredients for its own success. They discovered that their success stemmed from "CEO credibility, a senior team that manages expectations and implements strategy, and the availability of funds to execute the strategy and market drugs" (Grupp, Gaines-Ross, 2002). This interest in the components of its success came when the company's first in-house product was struggling in development and the company's stock price fell from $40 per share to $4 per share. The CEO licensed in a different product and the company began to see revenues. By early January, 2008 the company stock price had risen to $73 per share.

The company was ranked number 22 in the list of top 40 best companies by The Scientist Best Places to Work 2006 Industry (company website, 2008). Most highly ranked factors included remuneration and benefits, and the least highly ranked factors included research environment and communications (The Scientist.com, 2008). The CEO was named by *PharmaVOICE* as one of the "100 Most Inspiring People" and included in a list of entrepreneurs who are redefining the life-sciences industry through innovative approaches to improving technologies, processes, services, and ultimately patient care (company website, 2008).

I interviewed four company executives including the CEO, the Executive Vice President for Operations, the Executive Vice President for Research and Development and the Vice President for Public Affairs. The CEO and two vice presidents were men. All interviews were face-to-face and lasted approximately one hour.

Biographies of Interviewees

The CEO founded the company in the 1980s. He received his doctorate in life sciences and before founding this company served as senior research biologist in the medical products department at a major pharmaceutical company, where he was responsible for developing

research strategies for identifying novel agents. He has authored more than 100 publications in peer-reviewed scientific journals. The CEO is currently actively involved with major research universities and community and industry organizations and he holds several adjunct faculty appointments.

The Executive Vice President for Operations and the Executive Vice President for Research and Development (VP of R&D) both joined the company in the early 1990s. Before joining the company, they were employed at major pharmaceutical organizations. They each hold a doctorate in the sciences. The VP of R&D has published more than 100 peer-reviewed journal articles.

The Vice President for Public Affairs is responsible for the corporation's external communications strategy, including executive communications, brand and pipeline public relations, and ally development. Before joining the company in the late 1990s, the VP worked at a major pharmaceutical organization on brand public relations. The VP holds a bachelor's degree in biology.

Researcher Experience

I first contacted Company B in August 2008 and was directed to the office of Public Affairs. After multiple calls and approximately four weeks, I was able to speak to the VP of Public Affairs where I was able to explain my research. A few weeks later, I received a call that I could have a 30-minute telephone interview with the CEO. I contacted the VP of Public Affairs and explained that I needed a face-to-face interview if at all possible and requested more than 30 minutes. We agreed that I would phone the CEO at the time scheduled and would explain the research to him. If he agreed, I would be allowed to visit the company and the CEO. The call with the CEO was scheduled for early September. When I spoke to the CEO, he was very

friendly but also abrupt and had a no-nonsense attitude. We only spoke for about five minutes when he agreed and told the VP for Public Relations, who was in the room with him, to schedule time for me to interview him and other senior executives. Several weeks later, I received a call that the interviews were scheduled for November 15 and I would be meeting for one hour each with the CEO, the Executive Vice President for Research and Development, and the Executive Vice President for Operations. For both the initial phone interview and the in-person interview, I was never given an option on day and times, but given the specific day and time to meet. I requested that I be allowed to interview more than three executives and was told that after the first meeting, the Vice President of Public Affairs would try to arrange additional interviews.

My meetings were scheduled to begin at 9:00 am in company headquarters and I arrived at 8:30 to meet first with the VP of Public Affairs. The facility was in the suburb of a major city and was a new modern building. As I entered the grounds, it felt as if I were entering a research or academic institution, with a long, winding road through rolling hills. The large, main building was connected by a second-floor glass enclosed walkway to another large building. The building was relatively plain, but attractive. The lobby and public areas were nicely appointed, but not extravagant, except for a very large bouquet of live flowers. The receptionist was friendly and I only waited a minute while the administrative assistant arrived to escort me to the office of the Vice President for Public Relations. Everyone I passed in the hall was business-like, but friendly. The VP, dressed in a business suit, greeted me and escorted me upstairs to the senior executive floor where most of the office doors were open and administrative support staff sat in large, well-appointed cubicles in front of the executives' offices.

The administrative assistant for the Executive Vice President for Operations greeted me and offered me water or coffee. I was then welcomed into the office by the VP who greeted me

and offered me a seat on the leather sofa. The office was spacious, but not huge. The furniture was professional and comfortable and there were a few “Star Wars” toys on the coffee table and desk. The VP was very relaxed and friendly and quite interested as I explained my research. He was casually but conservatively dressed in slacks and a button-down shirt, with no tie. The VP asked several questions about the research and then we spoke about the success of the company and the leadership that lead to the company’s success. By the end of the conversation, the VP offered to answer any other follow-up questions by e-mail. After exactly one hour, I was escorted to the CEO’s office by the VP for Public Relations.

The office of the CEO was a corner office and quite large, perhaps two or three times as large as the office of the VP I had just visited. The CEO’s desk was at one end of the room, and the CEO, the Vice President for Public Relations, and I sat in a living room style area at the opposite end of the office. The CEO was extremely cordial, very confident, and focused. He seemed charismatic and charming and was an attractive person. He was also quite forthright and maintained constant eye contact. The area in which we sat was slightly messy with papers scattered on the coffee table. The CEO came across as very decisive, strong, and smart. I felt he would be difficult to approach unless you had something specific to say. However, later that day, I saw him in the company cafeteria with an employee actively engaged in the conversation.

We were not interrupted at all during the interview. As I listened, I could see how one would be inspired to follow him. He was not arrogant, but extremely confident in himself. He smiled and laughed and talked with very little probing almost non-stop for one hour. When I left, I had the feeling that he would not think of our time together as he was already moving forward with the day’s other appointments and concerns.

At precisely 11:00 am I was escorted by the VP for Public Relations to the Executive Vice President for Research and Development's office. The office was also located in a corner of the building, but not as large as the CEO's. I was kept waiting for about five minutes and then escorted inside. I was greeted by a friendly, affable man who looked like a traditional scientist/academic and who was wearing a sweater and slacks. The VP was dignified and friendly and the office was comfortable with multiple family pictures on wall. Just as the interview began, the VP received a phone call and I was asked to step outside. The call lasted about 10 minutes and after a sincere apology from the VP, our interview began in earnest. The VP was extremely candid and offered a tremendous amount of insight into the relationship between scientists and business professionals. I was told that the actual research laboratories were located several miles away because when the company needed to expand, they could not find enough space to house all the employees. However, the VP of R&D said that having the researchers away from the business people turned out to be a good thing, because it maintained the integrity of each culture. When the appointed hour was up, I was invited to stay to continue the conversation because we had started late. We continued to talk until almost 12:30 when the administrative assistant entered the room and asked whether I could join the VP for Public Relations for lunch.

I was escorted back downstairs and then asked to wait for about 15 minutes in a small conference room where I was given a bottle of water and the use of a phone. The administrative assistant returned and escorted me to the VP of Public Relations. The VP was very friendly and we walked across the building to the company cafeteria. The cafeteria was very much like a food court in a mall, with a variety of choices and selections. Many people approached the VP in a casual, friendly way and I was impressed with how open and outgoing everyone seemed to be.

While we were waiting for our food, I noticed the CEO was seated across the room and was engaged in an active conversation with an employee. I was surprised to see the CEO so open and approachable and eating with everyone else.

The VP and I took our food back to the office and ate at a meeting table in the VP's office. We had a casual, informal conversation that became very interesting. She discussed life as a female executive in a male-dominated world. She was clearly very loyal to the CEO.

While we began to talk, when she started to discuss leadership, I asked if I could record our conversation. Although this was not a scheduled interview, we were able to address my questions of leadership and success. When we finished, the VP promised to schedule at least one more day of interviews. Unfortunately, this never happened. Although I followed up on several occasions, I was notified by e-mail in mid-December that I would not be able to interview any others at the company. My impression is that the VP of PR wanted to make sure I spoke with people who were considered "appropriate" from a public relations perspective and it was becoming too difficult to arrange the logistics.

My overall impression of my one visit and four interviews was that the company culture is positive, the employees for the most part seemed happy, but the security around manufacturing and selling prescription drugs is tightly controlled. I did not speak to anyone other than those I was specifically arranged to speak with. I suspect the people I had been allowed to talk to were those most trained in talking on behalf of the company.

Key Themes from Interviews

I identified key themes from the interview with the CEO and then compared them with comments and concurrent themes derived from interviews with the company's other senior executives. Some themes were unique to these senior executives, and these are identified

separately. The following themes emerged from the interviews and are listed in order of prevalence: how to succeed, decision making, leadership, failure, change, risk, organizational processes, vision (including mission and goals), transparency, and conflict. The data from the interviews were further analyzed into a summary of how to succeed. The following sections include quotes from the interviewees as they relate to the themes. Some quotes will be used in multiple themes. The speaker in each theme is identified by title and number.

How to succeed. The CEO and the senior executives were asked to describe factors necessary for the success of Company B. The resulting themes included a culture that fosters an entrepreneurial spirit, the right team of executives, clear decision making, networking and working face-to-face with others, contingency plans, and an understanding that science is business. Most of the executive team has been together since the founding of the company, and some mentioned the concern they have regarding who their successors would be. All vice presidents interviewed described the CEO in very positive terms and indicated he is a charismatic leader.

I asked all the leaders how they envision the success of the company. The executives discussed how the company became successful and what was necessary to maintain that success. B3 mentioned the importance of scientists keeping a business focus. “Some younger companies…believe that science will drive them to success. And they forget that science is a part of the business. At the end of the day, in a company that’s funded either privately or publicly, at the end of the day, it’s a business.” However, all executives mentioned that a key component to the company was the leader and CEO. B3 added that the ability to understand both science and business was an important trait of the CEO. “So he was a very good scientist when

he was a scientist and he just had that extra something that he can visualize a much broader -- he can interact with the business group."

VP B2 stated, "[The CEO] is great. He really understands. He's a self taught as far as all the financial issues."

B4 also discussed characteristics of the CEO and described him as a "great leveler" that everyone looks to. She added,

> And he is the person who can see things that no one else can see. He's truly a visionary…a visionary sees things out there and everybody else is back here…So he pushes people beyond their comfort zone. He pushes them to go places they would never go on their own because he knows that it's possible to get there.

Entrepreneurial spirit. The executive vice presidents and the CEO all agreed that an entrepreneurial spirit is important to the company's success. The CEO stated, "And, you know, by nature, we select entrepreneurial people - risk takers. If we don't, then shame on us. Every once in a while, we sort of drift away from that, right? And then I have to make changes and come back to that." "In order to be successful you need to have an entrepreneurial environment" (VP3) and "For [the company] to continue to be successful, we need the entrepreneurs" (VP2). However, they expressed concern that as the company grows, it is more difficult to maintain an entrepreneurial spirit. The CEO described how it was easier to keep the entrepreneurial spirit when the company was small and not global. "How do I get that entrepreneurial spirit and attitude to my team in Warsaw, Poland, for example? How do you do that? And that's where the challenges lie. It's easy in this hallway to do that. It's really hard to translate that behavior to different cultures, different spots on the Earth." All the executives expressed a fear of becoming overly bureaucratic. The CEO stated, "That's probably the biggest challenge you have, as leader of a company, is to keep the culture moving in the right direction and not become

overly bureaucratic." B2 concurs, "I think what we try to do is avoid bureaucracy. As you get bigger, bureaucracy tends to creep in and that's probably one of the issues we struggle with."

Right team. Another area in which the executives agree is the need for the right team of people who are able to work well in a group. B3 stated "I think one thing that defines [our] success… is that many of us have been together for many, many years, which is unusual in biotech." B2 agrees, "If we are going to be successful, we have to get along as a team." The CEO stated, "the guys who have been here a long time are people who are not only, you know, sort of tremendous, accomplished individuals, they also make the group - the management group dynamic, better." As stated earlier, the CEO feels he does a good job of picking the right people who work well together. He stated "there's an individual dynamic and there's a group dynamic, right? You could be a great individual here, but if you don't work in the group -- if the group is not enhanced by your presence, it's not a better group because you're there, then it's not going to work here either, right?" The value of the team was addressed by B2 who talked about making sure "sure everyone's aligned with what it is we're trying to do and have open dialogue as to what issues are and what things you need to watch for, [and] to be transparent."

One of the VPs expressed concern that although the company has the right team now, it may be difficult to continue the success when the team moves on or retires. He discussed the importance of giving opportunities to those junior to him, so that they will be prepared to take over when necessary.

> What I think that we, as managers, have to do is try to give the opportunity to people that want it. That's the difficult thing. You know, at [the company], here, the difficulty is who our successors going to be and how do we train those successors and give them the opportunity.

Decision making. Decision making was another theme that came up when the executives discussed their success. "If we're going to be successful, we have to make a decision." The CEO

is clearly a decisive leader. As one VP stated, “Well, there’s consensus and then there’s [the CEO]. He doesn’t run a democracy. If we need to make a decision on this, he’ll go around and ask people what they think and then he’ll make a decision based on what he wants to do. We don’t take a vote and say, “Okay –‘’ what we do is that we all get one vote and [the CEO] gets 20.” Although the CEO is seen as decisive, he does not make decisions that others could and should make. “He won’t push the responsibility on one of us to make the decision if he is the one that has to make it, but he doesn’t do it based on what he believes. He gets a lot of input for that and he’s very methodical about those types of things.”

The CEO believes that decisions should be made based on information and not emotions. In fact, he stated, “I’m not an emotionally involved man. I don’t get really mad, I don’t really get happy. They’re all cold, calculated decisions.”

Culture/networking. The CEO especially discussed the value of a culture conducive to networking and working face-to-face with people. He states,

> It’s all about people. You want a deal done, you’re not going to get it done on merit. You’re going to get it done because they want to work with you, right? So you have to fly down and buy the guy dinner and go play golf with him and get to know him. I think it’s the same truth for your employees.

Another time he mentioned that company executives should not use e-mail as their main mode of communication. “You got two guys in an office next to each other; they’d rather send each other e-mails than get up and go talk to him. So the environment is poisoned with process and you stifle people’s ability to think and to be creative. They fundamentally lose their imagination. And that’s what you have to fight against as your company becomes successful.” Later the CEO again discussed the importance of face-to-face communication when he stated:

> You know, you’re only going to trust [name deleted], but if you really know her, know what her capabilities are, know what her weaknesses are, know what she can handle, what she can’t handle and you’re not going to get that through an e-mail and you’re not

> going to get that through a resume. You're going to get that through your interactions with her. You're going to take her out to lunch, you're going to have meetings in her office; you can see how she thinks. That's what makes – it's that kind of engagement you need to have. And if you don't do that, you will fail --fact.

The VPs also are concerned about maintaining a culture of open communication. "It's really hard to maintain the spirit of the company as you have gone from 50 people to 3,000 people." One VP talked about how important having an open-door policy is. "If we are to be successful, we have to be accessible."

Contingency plans. Several people mentioned that part of the reason for the success of the company is that the CEO had a contingency plan in place in the event of a problem with their first product. Indeed, their first product stalled in the USFDA, but the CEO had licensed another product at the same time that proved highly successful.

> I think you have to have a lot of stuff and plans. You must be smart enough to know when plan A is failing, you move to plan B. You can't think of plan B after plan A failed --too late. When you start plan A, you better have plan B and C in your hip pocket -- there's a lot of value in planning and scenario building and -- You never want to say, now what?

According to one VP, "too many companies fail because they only have one product in the pipeline, so we wanted to bring in another product in the event that the first product wasn't successful." He added that he encourages contingency planning within his group, "asking them the right questions, thinking of contingencies and not to micro manage the work that's being done, but overseeing it and make sure that we're thinking ahead."

The next sections of the paper will discuss secondary themes that came up during the interviews and will describe in more detail the complexity and interactions of related themes already mentioned.

Interaction. A company culture conducive to networking was viewed by all four executives as critical to Company B's success. This section delves more deeply into the

executives' views of the importance of interaction. The CEO stressed several times in the interview his philosophy of speaking directly to people. "It's all about people." The CEO said that he spends much of his time talking directly with people, "especially the new people." He wants to understand how the new employees think and work. The CEO builds a relationship of trust so that when a new VP has a big decision to make, the CEO is comfortable with the choice the new VP makes. He states

> They're managing $40 million budgets and they're making decisions. So you can't just bring somebody in because their resume is good and they have a lot of experience and say, Okay, you go do this, and leave them alone. I mean, if you do that, you have no clue if they're doing the right stuff; you have to learn about them.

B2 described interactions between the senior staff as both formal and informal. He mentioned that the formal meetings are important in make sure everyone is clear on the issues.

> [The CEO] has staff meetings once a month. I have weekly staff meetings. Part of the purpose of these meetings is really to foster the interaction between the various different groups. All these groups are interactive but sometimes you need to make sure that they're all hearing the same thing, or concerns of one group will affect another.

B3 also talked about different groups' ways of working together. He described cross-functional groups as an important part of product development, but there are complexities involved. There is frequently no direct-reporting within cross-functional groups. The team member's supervisor may not be on the team. B3 feels that a high degree of interaction is important with cross-functional teams because they are difficult to manage.

> Bringing the folks together, everyone, to make sure everyone's aligned with what it is we're trying to do and have open dialogue as to what issues are and what things you need to watch for, to be transparent and be a kind of, if you will, a coach or father or mother, right? You're a disciplinarian and you're the cheerleader, you're the brains behind the operation. You take accountability to the success and failure and those types of things, I think that's kind of what those -- these cross-functional groups do.

B3 also described the importance of truthful commentary within the teams or groups. He stated that he is not interested in having people tell him what they think he wants to hear. "I want

you to come in and if you think it stinks, tell us. I really want your critique. This isn't for show. This is for real. We don't have time to play around here."

Science-business interaction. Another important aspect of interaction discussed mainly by B3 (the VP of R&D) was regarding the interaction between scientists and business people. Because there was not enough space to build a new main facility that houses everyone, the laboratories were located about 10 miles away from the new company headquarters. B3 believes this situation has worked out positively because he feels that the different cultures of scientists and businesspeople are not necessarily conducive to a positive work environment. He described scientists as being excited by things that may frustrate business people to hear.

> The way we set up the company, we did it purposely so people didn't intermingle. If you're going to walk over there, [the laboratory] the environment's just totally different. [The scientist] will be just thrilled about a really clever experiment that suggests something might be possible in 20 years. But they don't think about the 20 years from a business point. They're interested in what happened today and what this means as far as the overall process of that physiologic event, et cetera. The application of that to a commercial product is years and years in advance.

B3 does not feel that the science is not appreciated or its importance recognized within Company B, but "it's just that trying to force the integration just doesn't work for us. I'm not sure it works for any company." He says there is no hindrance to scientists and businesspeople working on cross-functional teams or interacting in other ways, but in general he thinks that businesspeople think the science is "boring." Some businesspeople do find the science compelling, and B3 described meetings where the scientists are recommending a new chemical compound to be developed and "in general, the people who really interact at that meeting are the folks who really understand the science."

Decision making. Decision making was briefly discussed previously the section on how to succeed. The executives generally agreed that the CEO is very decisive and, in fact, the

corporate culture supports decisiveness by its executives. According to the CEO, "Leadership is making the tough decisions, making the right decisions and showing people how to get from point A to point B." However, the executives also indicate that they support allowing others to make their own decisions for their areas of responsibility. They also agree that gathering facts to make an informed decision is important, but consensus is not required. The CEO stated,

> I'd like to think that we have a consensus operation, but the truth of the matter is, it's consensus to a point. I'm willing to take opinions and consider them and build them into the decision process as long as it's going in the right direction. In the end, someone's gotta choose the direction, right? And that's never a consensus. So this is like a -- this is not a democracy here, right? It's a benevolent dictatorship. I don't know what it is, but it's not a democracy, right?

The CEO also described decision making outside the main headquarters as being local to the office involved.

> As a company matures and becomes global, those routine decisions by definition have to be delegated out. They're making those decisions on their own in Germany everyday. They do it everyday on their own. I don't know if their decision processes there are the same as what we use here.
>
> The CEO only intervenes if there is a problem.
>
> The guys in Germany will keep making their own decisions, as an example, the way they want to make them until there's a problem. I spend all my time with the guys around the fire, right? And the guys that don't need to see me, they have things going great; I don't need to see them either.

This culture of decision making filters down to below the executive level. According to B3, "there's an aspect of allowing individuals to feel empowered to make decisions, to go on different directions and to have an environment where that's accepted rather than, no, you can't say this or you can't do anything lest I tell you to do."

Despite the freedom to make their own decisions, the CEO believes that once new executives are faced with the complexity of the level of decisions they must make, they generally seek out others' opinions.

> Once they realize the magnitude of the decisions they're making, how it impacts the company and more importantly the livelihoods of all the people that report to them or the rest of the company, you know, they want another opinion. They welcome that other opinion because in the end, we're responsible for all our shareholders but all 3,000 employees - their livelihoods, their healthcare. We do all that, so if we make the wrong decision down the road, you know, people are damaged by that. Patients are damaged by that, right? And we can't -- investors are damaged. So we -- there's a great deal of consequence to the decision-making process in a company this big and one in the life science area.

B2 expressed concern about decision making in a larger corporation. He worries that as the company grows, people are more risk averse and decisions can take longer to be made with more people involved.

> In the old days, we can say, well, if an issue comes up, we call a meeting. In an hour it can be resolved. We still can do that, but a lot of the decisions -- people are more reluctant to make decisions and take risks. It's a big company mentality, you know, people -- you know, the worst thing for a company is to have no decision being made.

However, he stated that in his own group, they are able to still make decisions quickly.

> I pride myself and on the group, that we make our decisions pretty quickly within our group. I have to make a decision based on what I hear. And they all understand that. They're comfortable with it. Again, they're more comfortable --just make a decision, let's get on with it rather than just debate it for two months.

B2 points out that decisions can sometimes be pushed up to the CEO level and then the CEO's determination is final. "If you have one group that's not making a decision then the management team here will make the decision then. So, we'll get frustrated by a group not making a decision." In fact, this VP prefers a decision be made, even if he doesn't agree with it. "There are a lot of decisions made that I don't agree to, but I'll say, 'Okay, I'll support it.' So that's exactly the philosophy that we all have." This is an important point. The senior executives truly seem to respect their leader/CEO to the point that when he has made a decision, even if they don't agree, they respect the decision. "I don't recall a situation where I haven't supported a decision" (B2). The group values decisiveness but not to the point of being unwilling to change a

plan after a decision has been made. B2 stated, “We’ll go back and constantly re-address the decision, you know, but at least we have a decision based on what we found.”

Although the CEO has the final say in decisions, he allows discussion, disagreement, and debate around some decisions. According to B3,

> Decisions that are made are understood. They may not be agreed upon but at least they’re understood. And within that form if you can reach a consensus, that’s a positive thing. So it allows everyone input. They feel empowered to make an input. Sometimes we get some very heated debates and some would call it arguments but that’s okay. I encourage that because I say, in here we can do that. When we walk out, we’re one.

Leadership. The leaders themselves described their ideas of leadership and how they envision their roles as leaders. They define leadership as building relationships, setting an example, and making tough decisions. They also describe the need for the leader to be able to adapt over the life of the organization. The CEO states that

> Leadership is just an example, how you do things. If you do them right and you do them with a lot of integrity, and hopefully, make the right decisions, people follow that. If you want people to work a lot of hours, you better work more than anybody else. Can’t ask people to do things you are not willing to do, right?

He also describes leadership as making difficult decisions and claims it is much easier to lead through good times. “Companies go through cycles. It’s easier to lead companies in good cycles; it’s harder in bad cycles. I just think being --people follow people from a leadership perspective if they’re transparent in how they’re thinking, if they have a lot of integrity and if they have a history of making the right decisions.”

In the section on how to succeed, the CEO describes the need for a high level of interaction. B4 states that leadership also involves relationship building. “[The CEO] is one of those people who leadership must come naturally to him. No one had to tell [him] as a CEO, you need to make sure that you give up your time to the community. No one told [him] you need to get involved in these organizations. He’s just one of those people who ‘gets’ the relationship

thing. He really understands that things are done through relationships. And he spends a lot of his time building relationships."

The executives also discussed the importance of leaders being able to adapt to changing needs of the organization as it evolves. This factor was seen as particularly true for biotechnology organizations that are founded on science but that must evolve to a more business focus to generate revenues. B4 stated that he thinks "a mistake that a lot of biotechs make is that they believe that the science is going to lead to a commercial product, right, and that is going to continue to be funded by people based on promise. What we see is that's just not the case. So the leadership role of the scientist in an organization changes over time when -- should the company be fortunate enough to bring a product [to market]." He adds that eventually "the business issues overshadow anything that's going on scientifically because it ultimately comes down to money." The CEO said a transition occurs in the company as it evolves toward a more business focus. It is "fine for a scientist to run an R&D enterprise…but somewhere along that continuum, the priority shifts to the commercial -- to the business and that's where you lose a lot of scientist-founders because of that transition point, right? And it doesn't mean some of them can't do it. Sometimes they have a board that doesn't give the opportunity to try." And B2 adds that "It really depends on the individual's desire to learn." In other words, they all agree that scientist/founders can learn to run a business, but they have to be willing and able to change to a business focus.

Failure. The leaders described their views of failure. As B2 said, "It's very easy to manage success. It's hard to manage failures." The executives talked about the importance of taking risks, but they expressed concern over patient safety and said risks could not be taken

when it comes to patients. Finally, they mentioned that having a rich product pipeline and strong product development strategy were important to prevent failure.

The CEO struggles with the occasional failure of some newly promoted individuals in their job. “I’ve also failed sometimes giving people opportunities that they can’t handle then I have to let them go. And now I’m taking business risks. It bothers me when I take a risk on someone’s livelihood and put them in a job they can’t do, and I have to fire them. It was my choice to give them that opportunity.”

In addition to the CEO viewing promoting people beyond their capability as an opportunity for creating failure, he also has high expectations that, if not met, lead to dismissal. So, although there is a positive attitude toward risk taking within the organization, too much failure is not tolerated. “I think that’s the way cultures are developed and that’s the way people stay with you. You want the right guys to stay. I mean, wrong guys are just -- you gotta be a little bit ruthless about the stuff, right? They’re not my friends; I don’t go to dinner at their homes; I’m not the godfather of their children. Because they know that if they -- if this individual’s accomplishments don’t continue, or if the group enhancements don’t continue, I’m going to fire them. They know that every day of the week. It’s an interesting line, but that’s the way it has to be. And my board, I’m sure, feels the same way about me.”

When I asked the CEO if the company was tolerant of risk, he immediately pointed out that this is only true when it does not involve patient safety. “You will fail once in a while. You know, we’ve got enough systems in place to prevent catastrophic failures, but its okay if the guy in Warsaw fails at something. There are certain people that can’t fail here. Drug safety people can’t fail because human lives are at the other end of that, right? There are regulations that have to be followed.” Another time he again mentioned patient safety and risk, “The compliance side

of the world -- you can't fail that and then things to do with patients' lives and understanding what our drugs do to people and making sure they're using it correctly, that's our responsibility forever and that can't ever be, you know, sort of pushed aside or -- you can't take any risk on that."

When Company B had its first product in clinical trials, the CEO in-licensed another product. This proved to be an invaluable strategy, as the first product failed. The in-licensed product, however, proved very successful. B2 speculated that "too many companies fail because they only have one product in the pipeline, so we wanted to bring in another product in the event that the first product wasn't successful." B3 said that "If we didn't have [our in-licensed product], I'm not sure we would exist today, because it takes 12 years on average to get your own product out there; your probability of success is limited. And that's why a lot of companies have failed. We've had two failures. In the course of 15 years, given the size group we have, that's half or above the industry norm for compounds that have gone that far."

Product failure while in clinical trials is a major reason companies fail. Company B mitigates this risk by taking certain business risks to help meet timelines. They may have several products in clinical trials at any one time in the event that some may fail. B2 said "if we are going to file this NDA [new drug application] by this day, for me to make my timelines, I'm going to have to take some risk on some things that I am doing and if the drug fails, then the program fails, then we just lost a lot of money, but I can save a year by doing that."

Change. Company B and its leaders have undergone major changes over their careers and the life of the company. The three top executives that I interviewed were all originally trained as bench scientists but are now business executives. Change has been addressed in previous sections on how to succeed and the need to adapt. This section addresses areas of change that

have not been previously discussed: people don't change, but can be educated; the transition from the bench to business; some people's innate abilities that make them good in one area and possibly not in another; the evolution of the biotechnology industry; and surviving change. The leaders all describe the company as having gone through many changes, but that in the face of change the company has been able to adjust, survive, and thrive.

People don't change, but education helps. The CEO described his revelation that people can be educated, but fundamentally do not change. "People don't change. I've tried to change a lot of them; they don't change. So people don't ever change, but people can be educated. They can do a lot of things differently, but they are who they are and I am not influential enough to change who they are fundamentally. So it comes down to who you select to work here." Previously in this paper, the CEO stated that he is good at picking the right people, but sometimes he makes a mistake.

B3 agreed with the CEO that people can make a transition with the help of education. B3 described how he made the transition to business during a time he worked in a large pharmaceutical organization. That company offered him training to help him become a better manager. "[The] transition to the bench was done in an environment that was supportive because they had a lot people you can learn from. They had a lot of programs that help--two- or three-day seminars."

Not everyone is cut out to be a manager. B3 observed that different people have different skill sets and view the world differently. He appreciates the fact that each skill set has its own value and that when people with different skills come together, a product can be created.

I like a guy in research that sees a big pile of mud and he says, 'Wow, that's beautiful, because that's your creation, right? But once it begins to take form, they're no longer interested.

They know where it's headed because they're well beyond that. They want to go back and find another big pile of mud. Then you need a guy that wants to take forms saying, I know what to do with that. I can finish that. I can bring it to a point that now you can recognize what the art form looks like. Then you need a finisher. That's the guy who's really interested in taking that. Maybe when he sees a pile a mud he sees a pile of mud. But he can take and go, Okay, now we're going to really develop it into something. You need all those that have equal footing, equal ability for that and also that's what they're good at. And you convince them that's what they're good at."

Industry changing. B3 observed that the biotechnology industry is also evolving and changing. In the early days of the industry, basic science was highly valued and when scientists transitioned from pure research to commercial research, they were not viewed in such high esteem. Then, as the industry matured, it became the norm for many scientists to leave academia or research institutions to start their own companies. Scientists were no longer held in lower esteem and not viewed as "selling out." Government funding to the National Institutes of Health (NIH) also changed from pure research to research on diseases that could be cured. Money was also made available for funding start-up companies in the hopes of curing disease. According to B3, most research in the basic sciences shifted to more applied research.

> Things have changed dramatically. There is so much emphasis on profit and business now that's near-term. But the longer-term aspects -- and you can see that at the NIH where their funding is being lost --You can read in the rags that the United States is slipping as far as its leadership in science. It's the Chinese, the Japanese, the folks that are really coming along in graduate schools now.
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> It's an evolution of where politics or where the government is as far as funding. What pressures are on the NIH? What's happening to the scientific community? What's the hottest thing since sliced bread? And then I think influencing a lot of that for the science base, how many great academicians had this great finding and they think they can go out and make gazillion dollars? So they set up a company. They leave academia, they set this company up and as you pointed out, they fail. Sometimes, some of these guys make a lot of money.

B3 noted that many diseases will only be cured from discoveries made by basic research. “How come we don’t have cures for Alzheimer’s disease? How come we don’t have cures for this? How come we don’t have cures for that? Well, it takes money; it takes time; it takes people that [do] different science.”

Surviving change. B4 described Company B as being able to survive change and challenges ahead. She acknowledged that change is not easy, but the accompanying difficulty is just part of the process. “Because I do believe that if we prepare, if we work together, that it doesn’t matter what’s coming at us. We could get -- we could get beyond that. This company has a history of doing that, of surviving challenges, of thriving and even when it’s going through challenges. So clearly, the company can do it. But sometimes, it feels emotionally disruptive and, you know, it’s that whole thing about change -- It just doesn’t feel good. And if you get swept up by that emotion and don’t allow yourself to simply realize it’s just part of the process.”

Risk. The executives discussed risk and how risk-taking is acceptable in some areas of the company, but not when it comes to the clinic and patients. The CEO is a noted risk-taker, particularly in the early stages of the company’s history when he in-licensed an untested product at great expense, but the product ultimately became their leading source of income. As B4 stated, the CEO is extremely self-aware and self-confident. “[The CEO] had no doubt that taking that risk was going to end up in that reward. And he was going to do what it took to get there.” However, the CEO and the VPs also discussed no tolerance for patient and employee safety and the need for overall “prudent risk.”

No risk when it comes to safety. The CEO discussed concern for shareholders and employees, but that in the life sciences, there is an added burden of patient safety. He also stated

that Company B frequently exceeds the government standards for safety, and he only wants employees in the company who have a drive to make sure patients are safe.

> Every public company is responsible to shareholders and their employees. I think they should be responsible for their employees, right? But in the life science arena, the pharmaceutical arena or device companies or, you know -- you have patients' quality life and their lives in your hands. Well, you don't take any risk in that area.
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> You know, there's a standard that the world wants you to meet, but is that good enough for you? I mean, if OSHA comes in and says that four on-the-job injuries per thousand is standard, you say, hey, I'm at 3.6. Is that good? I think one injury on the job is too many here, right? So you have to have your own standards.
>
> So even though you're within the guidelines, that's not good enough. You gotta keep pushing it to another level. So you gotta get people who believe that here. For people who are fat and happy -- they have 120 patients die on your drug over a 10-year period because it's within what's expected, I'm not happy with that. I'm going to fire that person and get somebody else who's not happy with that.

Prudent risk. VP B3 described the CEO's ability to lower the overall risk of the company, partly from his prior experience in a large pharmaceutical organization. Even though the CEO did not function as a business executive in that organization, he obviously learned from the experience. "We had a compound which unfortunately didn't get approved and [the CEO] said, I'm not going to risk the business. He had an opportunity to [in-license a product.] So is there a balancing of risk? He wasn't influenced by the fact that it was exquisite science. It's going to make the company successful because he'd come from pharma and recognized that even in the best science only 10 percent ever make it to commercial product." B2 described the balancing of risk as "prudent risk. I mean, we're not cowboys. If you assume success in that clinical trial, then you start designing and preparing for that second trial." He said that Company B pushes the USFDA and will sometimes even submit a product for approval before they think it is ready to see how the USFDA reacts. The company uses this information as a learning experience and is able to more quickly meet the USFDA's standards for approval. "What we

need to try to push that envelope just a little bit and see if we can negotiate with the FDA for better conditions."

B2 described his understanding of risk in Company B as similar to the speed limit. "The speed limit is 55. But I'm will willing to go 65 knowing that I am going above the speed limit, but the risk of me getting a ticket is slim. Nobody is ever going to stop me from going 65. And I think we as a corporation have to go 65 miles an hour."

Organizational processes. As previously discussed, the company executives were all concerned that, as the company grows, it will become too bureaucratic. However, all executives wanted to learn from the bureaucratic processes they experienced in their pharmaceutical background and either avoid these processes, or incorporate them. The CEO stated, "If you want to lead people, they gotta believe that they're participating in the process." B3 said, "We take the best of what we learned because some of it's very good. These companies aren't successful because they're not well-managed, right, but also leave behind some of the things that are irritating to us. And so we paid a lot of attention in the processes that we put together."

B3 also described processes he had learned in his previous experience on teams and how he incorporated those processes into Company B. He talked about learning how to form and empower teams. "This is what a team does. This is how a team operates. This is what your responsibilities are. We're trying to take what many of us have seen and really make it into something that has meaning, right?"

Vision, mission, and goals. The executives did not discuss vision, mission, and goals extensively. The only reference the CEO made was, "the goal is to be wrong less so often than you're right." In fact, B2 stated that time shouldn't be wasted writing a mission statement. "I sat in a meeting once, and I spent a half hour discussing what their mission statement is going to be.

If you talk to a lot of the management at [Company B] or other biotech companies, most of us hate the mission statements. You know, the time it takes you to generate a mission statement, you could've successfully done a lot of work. If you don't know what your mission is then something is wrong with the company."

Later, B2 addressed the company vision, "We used to say the vision is to be the next Amgen or the next Genentech. [But] it's such an evolving company. I mean, the vision or the mission is to continue to be successful -- to grow the company. We don't have a path for doing that. We are going to acquire companies, we are going to have to have internal growth and we have a five-year plan, but that exact path of how we are going to grow and be successful is going to change based on the circumstances. So, I guess what the general goal is, is to continue to be successful, to grow with the company, to double sales, double the size of the company. That's the mission or the vision of the company."

Transparency. Although there are few direct quotes regarding transparency, when I was talking informally and without the recorder running, the word, and the concept, came up several times. The culture at Company B seems to suggest it prides itself on transparency. (Although my time with the company was so tightly controlled, I wonder if this is truly part of the culture, or something that is talked about more than practiced.) The CEO stated, "People follow people from a leadership perspective if they're transparent in how they're thinking." B3 also discussed the need for transparency as important to success in helping to create buy-in. "Bringing the folks together, everyone, to make sure everyone's aligned with what it is we're trying to do and have open dialogue as to what issues are and what things you need to watch for, to be transparent." Later, he said you will "get buy in, if you're transparent, if you actually discuss the issues it takes a lot of time so you have to be willing to spend time to do that."

Conflict. Only one executive discussed conflict. The others did not bring it up and the subject was not part of the interview template. However, the executive who discussed conflict felt that it was handled in a mature way at the company. There was general agreement that the senior executive team members have a strong, positive relationship with one another. It would have been instructive to have had the opportunity to talk with more junior members of the organization to gain a clearer picture of how conflict is handled within the organization as a whole. B2 stated that "there are guys who work for me whose goal or objective is not to get me involved in settling disagreements. So they're going out of their way to try to get these things settled." Later, he stated that his division was composed of sizeable groups, and that "part of their mission is that, if there were issues coming up, they should be able to solve them, and that's what they do. [If this doesn't happen] usually then we will sit down. We'll get somebody in HR and I will try to mediate it through."

When talking about conflict among the senior executives, he stated,

> I think 'conflict' is too strong. We have a number of disagreements, but we all understand where we all are coming from, and where we want to go. So we have the maturity to work out those disagreements. We've had some heated debates, but the next day we're buddy-buddy again…we're all opinionated-type A individuals. But we don't take it on a personal level.

Summary of Findings

Company B is a large, successful biopharmaceutical organization. They have grown to be a leader in the industry. One of the leading concerns of the organization now, is how to sustain this success and growth. I interviewed 4 senior executives in the organization. Major themes that emerged include how to succeed, decision making, leadership, failure, change, surviving change, risk, organizational processes, vision, mission and goals, transparency and conflict.

Company C, Racing For Prevention

Introduction

The employees interviewed at Company C believe that success means saving lives. Company C is a non-profit product development partnership (PDP) established in 2002 to develop products that prevent the transmission of a specific deadly, infectious disease. Company C works to accelerate the R&D, commercialization, and availability of a safe and effective drug product for use in developing countries. The mission of the company is not to make a product that generates sales, but to produce a product that prevents disease. According to company literature, "development cannot be considered successful unless new drugs reach the [people] who need them. [Company C] is laying the groundwork now to ensure that [the drug], once developed, can quickly get into the hands of [people] in developing countries."

Company C's development partners include academic institutions, major pharmaceutical and biotechnology companies, and leading non-governmental and international organizations. The company screens compounds, develops clinical trial sites, conducts clinical trials, identifies international regulatory pathways, and establishes manufacturing and distribution capacity to ensure rapid access to the product as soon as it becomes available. The company currently has two main drug candidates that it hopes will enter phase 3 clinical trials by 2010. Company C also funds, co-funds, and leverages resources to support the drug development projects of other organizations. A primary objective of the organization is to generate money to fund research and development.

What is a PDP?

A PDP is a non-profit organization that combines public and private funding to speed development of drugs to fight neglected infectious diseases. Neglected diseases are generally

diseases that affect under-developed countries. Drug companies do not invest heavily in cures for AIDS, malaria, and tuberculosis because they are unlikely to generate a profit. Company C was one of 24 organizations that the World Health Organization (WHO) recently studied to measure progress and to determine what challenges these organizations faced. The WHO found that more than $1 billion was donated to fund the 24 PDPs working to find new drugs to fight neglected diseases and more than 60 percent of this amount was contributed by the Bill and Melinda Gates Foundation (WHO, 2008). Company C has received more than $200 million in funding from 11 countries and numerous foundations, including the Bill and Melinda Gates Foundation.

Biographies of Interviewees

The CEO founder of Company C received her doctoral degree in microbiology from the Harvard School of Public Health. Previously, the CEO was Scientific Director for an international non-profit organization in disease prevention. Prior to being scientific director, she worked as a senior scientist at the National Institutes of Health (NIH).

The Chief Medical Officer (CMO) is responsible for all clinical trials and international clinical site development for Company C. Prior to joining Company C, she worked as a clinical research investigator for more than 20 years. She also worked for a major contract research organization as the head of business development. She earned her medical doctoral degree in Africa.

The Chief of External Relations (CER) is responsible for all external outreach. Prior to joining Company C, she was a senior legislative advisor for the U.S. House of Representatives and Senate specializing in foreign policy and national security. She holds a master's degree in International Service.

The Chief Financial Officer (CFO) is responsible for financial management and also oversees operations and human resources. Prior to joining Company C, he was Executive Vice President and Chief Financial Officer of a non-profit social marketing organization. He worked internationally in management for other non-profit organizations and holds a master's of business administration.

The Executive Director for Research and Development heads the research component at Company C. Prior to joining the company, he was Vice President of Research at a biopharmaceutical organization and he spent three years as a research scientist at the National Institutes of Health. He holds a doctoral degree in microbiology.

I also interviewed the former Chief Science Officer (CSO) of Company C who has a doctorate in medicine and was a practicing pediatrician. He left his practice to start a biotechnology company that he later sold. He was CSO of Company C from 2002-2006 when he left to start another biotech company, but he still consults to Company C.

Researcher Experience

I was first introduced to Company C when I was asked to develop and facilitate a leadership retreat for senior executives. The organization was undergoing rapid growth and was experiencing growing pains as they increased their employee headcount from approximately 40 to 100 employees. I facilitated two retreats over a 12-month period and was also asked to be an executive coach to one of the executives interviewed for this research. Although Company C is a non-profit organization, they are similar in many ways to for-profit organizations. The company and its leaders experience many of the same issues that face other biopharmaceutical organizations with scientist/founder leaders. I contacted the leader by telephone and explained my research. She said she would be happy to be interviewed and she gave me permission to

contact the other executives. I spoke personally to each executive and asked whether I might have a one-hour interview with them and they all agreed.

Company C is located in a downtown high-rise office building of a medium-sized city. It is located above a subway stop and has underground parking. As I emerged from the elevator, I entered a walking plaza, with shops and pedestrians hurrying by. I entered the office building and was greeted by a guard who asked me to sign in. The lobby of the building was nicely appointed with a large desk for the guard and several potted trees. The guard was friendly. I was sent to the second floor where I entered another reception area. This area was larger than the lobby and a receptionist greeted me. My first appointment was called and I was escorted by the Executive Assistant to the office of the Chief Medical Officer (CMO). She was in town for company meetings; her main office is located in South Africa, where many of the company's clinical trials are taking place. She met me at the door but asked me to wait at a small conference table while she completed some work on her computer. The office was decorated with African art and there was a large window that overlooked the city street and subway stop. I had been waiting about ten minutes when the CMO joined me and apologized for keeping me waiting. She is an attractive, quiet, polite woman who spoke softly but with an intensity that made me feel she was quite passionate about her work. We had spoken for about 45 minutes when the administrative assistant interrupted and said she had another meeting to attend.

I came back a few days later to formally interview the CEO and the CFO. I first met for one hour with the CFO. His office was quite large and spacious, with a wall of white bookshelves. The shelves were not filled, and he explained that they had just moved into the offices a few months prior. The CFO sat behind his large desk and I sat in front of the desk. He kept his distance from me as he did not feel well because he had a bad cold. However, we talked

for a full hour and he volunteered that I could return if I had additional questions. After our time together, I was escorted by his administrative assistant to the office of the CEO.

The CEO's office was across the building from the CFO and down the hall from the CMO I had met a few days before. The CEO's office was similar in size and shape to the CMO, but felt smaller than the CFO's. The office was pleasantly furnished and also decorated with African art. The CEO did not keep me waiting, but greeted me and offered me water. We talked without interruption for one hour. When I left, she hugged me and wished me well with my research. During our time together, she impressed me with her passion regarding the work the organization does.

About a week later, I returned to interview the Executive Director of Research and Development. When I made the appointment with his administrative assistant, she called me several times to change our meeting time. The director's main office and laboratories were located about three hours away from headquarters, but the director had other appointments at the headquarters the day we were to meet. I waited in a small conference room off the reception area of the company for about 20 minutes for the director to arrive. When he finally came, he was rushed and apologized profusely for keeping me waiting. At first, he seemed harried and concerned about the confidentiality of our interview. After about ten minutes, he seemed to relax and appeared less rushed and nervous. After our one hour talk, I turned the recorder off and as we were both leaving the conference room our conversation turned to communication within Company C. I asked if we could continue with the recorder on and we sat down and talked for another 15 minutes.

My next meeting was to be the following week with the Chief of External Relations (CER), but she was unexpectedly unable to make the meeting and we rescheduled two weeks

later. Our meeting was scheduled for 4:00 pm. I arrived on time and was escorted to her office by her Administrative Assistant. The office of the CER was next door to the CEO and was the same size and general layout as the CEO and also had African art on display. The CER greeted me cordially and asked if I minded if she ate yogurt while we talked. She had had a very busy day and had not had lunch. We talked for almost an hour and a half. She was extremely articulate and I could see why she would be the spokesperson for the company.

The last person I interviewed regarding Company C was a consultant to the company who was the original Chief Science Officer (CSO), but was now a scientist founder of a different biopharmaceutical organization. I had met the consultant while facilitating one of the leadership retreats. He agreed at the retreat for me to contact him by phone to interview him. I interviewed him by telephone and he was extremely helpful and cordial. He also responded quickly to follow-up questions I had. During our telephone interview, he volunteered to introduce me to a venture capitalist who invests in biotechnology firms. The consultant made an e-mail introduction, and I was able to interview the venture capitalist. This interview is presented in the section on consultants.

Key Themes from Interviews

I identified key themes from the interview with the CEO and compared them with comments and themes derived from interviews with other senior executives at this company. The following themes emerged from the interviews: Leadership, mission orientation at non-profit organizations, science-business interaction, teams, challenges, communication, risk, success, and failure. The following sections include quotes from the interviewees as they relate to the themes. Some quotes will be used in multiple themes. The speaker in each theme is identified by the letter C and numbers 1-6.

Leadership. The senior leaders at Company C described how they view the role of leadership within the organization. C1 said she viewed her role as "part cheerleader and part mother." She explained that the cheerleader role involved keeping people motivated, and mother role involved making sure the employees are happy. "You don't have to buy in for life. I just want you here totally committed, totally dedicated, and when it stops being fun, you need to leave." She also said "I'm trying to do what I like best in some ways. If I'm happy, most other people are going to be happy." C2 also mentioned that employees should be happy in their job or they should consider leaving. "I always tell the people you must have fun at work because if you enjoy your work, you will give a good product. If you are not happy at work, you must either address it or make a decision why you are not happy and either that might mean you need to move on or working in another position."

C3 had consistent opinions regarding motivating people as being an important part of leadership in Company C. "My ideas of leadership are keeping our team motivated in absence of a product. If we had a product we could say, 'We know that this works;' it would be a lot easier to say, 'It works; therefore, we are going in this direction.'" She said that because the political climate in the areas where they conduct clinical trials is so volatile it is frequently difficult to keep everyone motivated.

> Right now in Kenya, things are really falling apart [politically]. We have a couple of trials there. It is scary; our researchers are vulnerable; our participants are vulnerable. We have to keep saying to people, "Just because that is happening in Kenya does not mean that it will happen across our trials. Even when it does, stay with me. We are going to figure this out." So our role is confidence-building in the face of the unknown, which is fundamentally science anyway.

C1 described another role of leadership as being to make sure the senior executives have the right experience to supplement any gaps in knowledge or experience she may have. She used herself as an example of not having enough management experience, and how important that

experience is in being able to manage others. “If you can manage people and you can identify what you don’t know, then you find the people who know what you don’t know and you figure out how to manage everybody.” C3 also discussed the importance of the leadership sending out the right political messages. Her background is in international relations and much of her role is to interact with different governments and constituencies.

> Before I came to [Company C] my work was in issues truly of war and peace, macro-international relations issues. So since [Company C’s] work is international, my role is to keep that voice of our international relations, our strategic partnerships front and center in the work that we do because, fundamentally, scientists do not think that way.

C2 described leadership in many ways including “leading by example,” “setting clear expectations,” and helping her employees be developed professionally. “I see myself more as a development type of leader than just being an autocratic leader. For me, it is important to really develop the people.” She also described leadership values that are important to her including loyalty, integrity, honesty, respect, and trust.

> The values that are extremely important are loyalty and integrity, especially integrity. By integrity, I mean honesty and that you can be able to trust each other in a team and as a leader you must be able to trust your employees, they must be able to trust you. And respect - that mutual respect within a team; it does not matter the role of each team player.

C5 mentioned the importance of leadership enabling people to perform their jobs.

> As leader, I see my responsibilities as focusing on enabling those who actually do the work to have everything they need to successfully do it. If they need resources, if they need clarity of objective, if they need external expertise, if they need structure modifications, if they need additional staff - all of which enables them to do what it is that they were hired to do in the first place.

C1 said that admitting lack of knowledge is important, but so is the ability to learn quickly. She has worked with people who feel “if you’re at the top of an organization, you think you’re supposed to know everything.” She readily admits that she does not know all she needs to know but that she is good at learning and finding people who do know what is important. Others

describe the CEO as “human,” “self-effacing,” “technically astute,” “charismatic” and “high energy.” C3 stated, “If [the CEO] takes you on as a senior manager, she listens to you.” C6 noted “She has no problem saying, ‘That guy is smarter than me,’ or ‘That woman knows more than I do here. Let’s hear what she has to say.’”

C3 also said that the CEO is excellent at being able to talk with others about the mission, as separate from the scientific and technical aspects of what Company C is doing. “Her particular talent is being able to pitch a message in just a way so that the average person listening does not get lost in the technical stuff.” C4 described the CEO as being “mission driven” “credible,” and an “excellent spokesperson” for Company C and that she “personifies the field.” C5 said that the CEO is a “good representative to the cause.”

Several executives described the CEO as not being egotistical. C3 said she has a “healthy, but not pretentious ego.” C4 said she is not “egocentric” and C6 agreed that she is “open” and not “ego-driven.” C6 described the CEO as being a “quick study,” “personal,” and “decisive.”

He also mentioned that she “has no problem being wrong.”

The CEO sometimes worries that the senior managers are “not a real team.” She states that the senior managers are not doing the job for “their ego,” but “must be totally committed” and mission driven. C2 noted that there are different styles of leadership within company B. She said because she is located out of the country, it was difficult for her at first to feel part of the team. However, she noted that within the senior leadership there is a “freedom to share your ideas and implement it” and she feels “trusted” to do her job. C2 added that when someone makes a mistake, “they will support you and really support you in everything. That was a wonderful experience.” C2 also commented on the lack on internal politics within the organization. “There was no power game; I really enjoyed that. The fact that you are aiming for

the mission, do your job, empower your people to do their job and there is no competition. I did not experience internal politics." C3 said that the senior leaders are quick to react and adapt to a changing environment. "We are the types of people that can quickly and intuitively look at situations."

Experience is an area about which many expressed concerns. Some executives felt they have the right amount of experience, but C1 freely admits she is "not a business person." She told donors,

> I've never run an organization before. So, you've got to bear with me. You're going to be asking me questions that I don't know how to answer because I've never done this, but I guarantee you, I will figure out the answers by making sure I've got people.

C1 also admitted to being surprised by how much the act of 'leading' is "all about people and personalities."

C3 is not concerned about lack of experience, in fact she feels the opposite. "It is that vision right there carrying people to that next step that makes people want to work for you and with you. And that is based on experience. I think it is just the ability to be intuitive and informed in an empirical way at the same time." However, C4 noted that "No one has done this work before." He believes that the CEO has a "lack of experience running an organization" and also "lacks experience dealing with senior people." However, he also stated, "I don't see that as a major problem at this point."

C5 is more concerned about the lack of experience with the CEO and other executives when it comes to drug development. He said that he is hiring "lower level people with product development expertise." He did state that he "would be happy to step aside if someone came in and said, 'This is a new management team.' It has got experience in developed world marketing, whatever -- prevention, products of regulatory approval."

Mission orientation at non-profit. Company C is funded by domestic and international government funding and through charitable organizations. C5 stated that the amount of money they receive from the U.S. government is low compared to other donors. “Part of our issue is the complexities of the current political situation in the U.S. [However, the disease] funding has done pretty well. In general, people are somewhat surprised that it has been as good as it has.”

The main difference noted by the executives in the organization being non-profit, as opposed to for profit, is that the employees are very much mission driven. According to C3, “they want to do good on Earth.” C4 stated that it is not “pursuit of money,” but, “all about trying to get to the end-mission.” C6 stated that in a non-profit, “followers are enamored with the mission.” However, both C3 and C6 felt that there is “not much difference in leadership.” C3 stated “A leader is a leader.” C6 said that there is a perception that non-profit organizations may have “lower performers” than for-profit companies, but he felt this was definitely not true with Company C. C3 stated that the organization performs more like a public sector company. “So in many ways, we have brought ourselves like a private sector but with that public sector zeal and accountability; want to do good on the earth - that is who comes here.”

C1 also stated that the people who work for Company C need to be mission-oriented and not too concerned about “little annoyances of day-to-day working life” when their mission is so critical. “That’s the cheerleading part -- constantly reminding people that there is a mission here and that’s what we need to focus on and just remember that there’s a broader mission that we need to be focused on.” She stated that when she interviews new employees she is looking for someone who believes in the mission. “If they don’t know anything about [the mission] they’re not here for the right reasons.”

C4 defines success "with respect to that mission, success is just getting there as quickly and efficiently as you can get." He stated that the company must "do whatever we think we need to do in order to better stay on track toward that mission." He added that with the instability of governments in Africa, he is concerned that they may not be able to complete their research.

> That means that our mission will be delayed and more costly to achieve by years and hundreds of millions of dollars. And [there are] a lot of very tense feelings around being used as research guinea pigs. If public sentiment that's misinformed or ill-informed sort of gets out of control, and the politicians get a hold of it, then we could find ourselves being curtailed in what it is we're able to do.

In addition to being mission oriented, Company C is also focused on specific goals that are similar to for-profit organizations. C6 stated that the company has been very successful in reaching its goals so far, including raising money, licensing in drugs and to a certain extent setting up its clinical trials programs. He stated that "on the whole, very successful in what are pretty typical of any start-up being for-profit or not-for-profit."

Science business interaction; speed versus quality. There is a struggle in Company C around the need for speed and the need for quality. The scientists are generally perceived as wanting to continually tweak the product and the business people are perceived as pushing too fast. As discussed previously, the CEO is strongly mission-driven and her goal is to get Company C's product to the clinic and to prevent disease as quickly as possible.

> I won't let speed be the enemy of quality, and [there is] the perception that quality is compromised. So the metric that I use is we don't need a perfect product. We need a product that is good enough because women are dying. So, 'good enough' doesn't mean that it couldn't be better. Good enough means that it is not going to cause harm; that women will be protected and then you can spend all the time you want in the world perfecting it!

The CEO added that the issue of speed over quality is particularly true with scientists who may feel that the push for speed can be unethical and is more about saving money. "There gets to be this perception that if you're pushing too fast, you don't care about the product really.

You don't care about safety. You just care about dollars. So there's an ethics judgment that gets put in here." She also stated that the R&D group's perception of success and failure may be different. The focus in the organization is to get the products approved as quickly as possible and this sometimes means moving forward and then being told by a regulatory body that they must go back and redo some of the tests.

> I won't compromise on risk to the woman, but it's not just that. It's also an interpretation of failure because if a regulatory body throws something back to you and says, I want you to do this. The folks who are in the R&D program who would have said, you know that's what we should have done the whole time, feel that they've been made to fail by management. And so it's this notion of failure.

C3 said that scientists are often uncomfortable with the speed in which the organization moves. C3 stated that Company C has a "priority of moving fast; roll up your sleeves and do not let any boulder get in your way kind of thing. Whereas, [the Director of R&D] is far more plodding so [the CEO] has probably overridden his decisions and there has been some blood on that." C3 also pointed out that at because Company C needs to balance politics with sciences "It sometimes can rub the wrong way scientifically, but we work that out."

C6 noticed the same problem regarding the perception of speed and quality. He stated that "There often is a big clash there and it is on the surface just that the business people want to get the product out the door and the science people want it perfect before it goes out the door." He added that there is an adage in the industry that "at some point you have to shoot the engineer. Just get a product out the door realizing that it will go through a number of revisions." C6 feels that there is a "communication issue and a personality issue, which is unique to [Company C]. They are just being told to get ready as fast as humanly possible but not to push it out the door until it is ready."

The CEO, however, does recognize the importance of the scientific perspective. She stated that scientists are more aware of details that may be very important that she might miss. "To some degree, you want scientists to be scientists. You want them to pick up these nuances and these signals that you may be missing from the 30,000 foot view." C3 believes that scientists do not always understand what the role of the business people are. C3 stated that one scientist frequently says to her, "I do not get what you do." However, she pointed out that as a business person she works well with the scientists and they are working together to better integrate their functions. "He and I have agreed that I'll go up to [the scientist's location] and do a presentation and give them a notion."

C5 feels that there needs to be even more integration of science and business. "I believe that there needs to be an overall integration of clinical, R&D, and regulatory." C5 says "the lack of strong integration between the different departments, in terms of cohesiveness for the working relationships between the members of the groups and representations to the outside, is extremely, extremely important." C5 noted that in large pharmaceutical organizations there is more of a "them versus us" attitude, but it is not as pervasive in Company C because they are not so large. C5 feels that the organization may need to be restructured to optimize the possibility of success. "You now need to configure this organization with the best possible people for a successful one shot."

Teams. The CEO is also concerned that there is interaction between all the functional areas, not just between the scientists and business people. She wants to ensure that people do not just complain, but are "learning from each other, sharing experiences, sharing frustrations. We're going to facilitate those kinds of interactions."

As described previously in this chapter, the CEO partly views her job as that of a parent making sure people are happy and are part of the team and the overall mission.

People want to feel part of a mission, part of a family that's doing this, that you're not out there –- I mean some people like to be pioneers and work solo, but I think most people would prefer to have a team approach, that everyone's kind of getting together as a family.

C3 states that without having smart people on Company C's teams, they would not function as well. "I have a very smart team. The Clinical folks are a very smart team. The Project Development folks are a very smart team. And the Finance team. But if we did not respond to events in a very credible way both with motivation and substance, data - because that is what speaks to most of our teams - we would be lost."

Challenges. As Company C races toward finding a product to prevent disease, they must, of course, first test the products in human subjects. They are currently in Phase 2 clinical trials, which is testing efficacy (how well a drug works at the prescribed dose). However, according to C2, "We are calling our safety studies Phase I/Phase II and the reason for that is because of our numbers of participants. Usually Phase I studies are at less than 90. We are conducting our safety studies between 150 and 350."

There are always concerns that because of political upheaval the trials will stop. The external environment in which Company C participates is volatile, and governmental changes in African countries put clinical trial research at risk. C3 explained that she has been going to Kenya for almost 20 years. Recently, there has been a severe downturn in the Kenyan economy that could significantly affect Company C's work. "The last time I was in Kenya, for example, in May, it was so obvious that there was such a degraded economic environment and such inequity

and yet so much potential that it was ripe for political combustion." Despite the political turmoil, Company C is still proceeding with their work.

> [The clinical trials managers] are still trying to make sure their participants can meet the standards of accountability to the trial leadership team. All these kinds of things have to keep going or the trial has to stop. If it stops, what does that mean for the protocol of the trial, the ethics of the trial, et cetera? These are big implications. So what if we lost the results of the last year in a heartbeat like that? That is really painful for everybody that has invested, and we would have to start over, scratch our heads, figure out what to do. Do we have a data gap that can be filled? This is the science part of it and then you have this human part.

C3 states that part of the leadership's role is to make sure people on-site in politically unstable countries stay motivated, yet at the same time, remain extremely careful. "But that is our leadership role; it is just to say, 'We have to take everything into consideration and take your well-being in mind, take the well-being of the study in mind,' all these things. But that is our role."

C4 explained that "there's a political environment out there that is more and more hostile to doing this kind of research in resource-poor settings or in South Africa, specifically." The reason Company C does clinical trials in Africa is because there is a high incidence of the disease they are researching. If they are not able to stay in South Africa, "then we're going to have to hit other places, and that becomes more and more difficult. So I see, internally I see [Company C] building the capacity to be able to do it, but externally I see an environment that may be turning more and more hostile to being able to do what we actually need to do." C4 said that in some ways the clinical work is even more important than the basic research. Because "even if we made a product, we wouldn't be able to do anything…unless we are able to actually conduct these trials." C4 also worries about the instability of many of the countries where the clinical trials are conducted. "But if there's no clinic to get into, then there won't be any

[product], so that's why the importance is to set up these research centers, half in South Africa and half elsewhere, for the political risks."

Communication. Partly because of the organization is geographically spread out, communication is particularly challenging for Company C. The company has grown substantially in the past year from about 40 people to almost 100. The company headquarters is located in an urban center, but the scientists and researchers are located approximately 150 miles away. There is another main office in South Africa, with additional sites in Europe and also across Africa with clinical trials sites. C1 stated that as part of the end-of-year evaluations, the senior managers "discussed how we're going to get different teams working together, where people are going to go." The CEO regularly travels to South Africa and to the R&D site three hours away. She states that "We've just got to acknowledge that part of the success in our work means that we've got to travel to see people. And that for certain people, it could mean once a year team in-person meetings. For others, it's going to mean quarterly or even bi-monthly."

As the company has grown, the senior executives have begun to meet regularly as a group. A goal of the group is to open communications. C3 stated that because the company is so spread out, without senior level communication to all employees, "pretty soon the gossip is spreading around." The chief executive meetings no longer include the senior management, but just the chief officers, and some senior managers feel left out. C3 states

> That has caused ripples because then anybody underneath of us says, "Well, the chiefs never used to gather like that and that means, therefore, the next layer down is not as important," which is not true; it is just a growing pain. So that is one way. Then, we have quarterly all-staff meetings, which are really cumbersome. We have come to terms with the fact that we will probably never all be in the same place.

C3 also noted the effects of rapid growth on the organization. "I think we are going through some growing pains now about supporting each other at the very senior level and that

has another unintended consequence if the next level down does not feel like they are part of the absolute intimate conversation. So we are struggling with growth."

Another problem with rapid growth and communication is the increase in e-mail. C3 said they have "way too much email. Just to give you an idea, [the CEO] and I now have three administrative assistants supporting us." C5 states that communication is a "real challenge when the primary mode is e-mail or telephone conferences. Things can be resolved in two minutes by dropping to someone's office." C5 commented that not being able to see people face-to-face is

> a real issue and you miss out on body language and sentiment in an e-mail communication, which puts people in a defensive mode or in an overly optimistic mode, and then, you are re-tracking because you are digging your way out of one or the other, which you have misread. So I think it is a significant challenge for an organization, particularly organizations moving as fast as this. You wind up managing the dynamic as much as anything else.

C5 also mentioned that there are sometimes surprises associated with not meeting face-to-face. "You have so many e-mail communications with so many people for so long and you get all kinds of preconceived notions who they are and what they look like. And then, you are shocked when you actually see them."

According to C6, the difficulty between scientist's need to continue to work on a product when the business push is to move the products along the pipeline may cause a communication problem. "They are just being told to get ready as fast as humanly possible but not to push it out the door until it is ready. And so that is a perception and I do not think it is a real issue there but it is a communication problem." He thinks that if the senior executives communicate more fully and regularly, some of the tensions between the scientists and business people may lessen.

Employees at Company C are frustrated by several things. Being pushed to work very hard and fast causes stress and feeling overworked. C1 understands these frustrations and even hopes the workload can lessen. However, she stated that "if you're really much happier

managing a smaller portfolio and you still want to stay here, you can do that because we can hire in a chief and then you can function at that. But if you don't then you really need to think about leaving." C5 is frustrated by tensions around time, money, and quality.

> [Company C] has got a lot of money so we do not care about what we spend, and time is the dominant factor. I fear that we go so fast, we risk quality. I get frustrated by the fact that time rises to the top again and again and again here. I do not think you can rush - beyond a certain point - the development of regulated products.

C5 is also frustrated by a perception that not everyone is listened to in the organization.

> There are people in the organization who do have relevant experience who should be listened to. I do not think that [Company C] does a good enough job of empowering those people with the expertise, they were allegedly brought in to actually use that expertise.

The CEO is aware of these frustrations and said that although other opinions are taken into account, the final decision rests with her and her judgment.

> I don't think there's ever going to be a right or wrong way to do it, and so I will obsess a lot more over information about people decisions. One thing I've learned the most is that you've got to put the organization first, but there's also a way of handling people with care so that it is as much of a win-win as possible.

Company C faces some unique culture issues. There are obvious cultural differences between the employees from South Africa and those from the US. The CEO stated that these should be met "head on." One issue the CEO described concerned a black American employee feeling uncomfortable when the employee visited the South African offices. The South Africans that work in the office are all Caucasian. "Are you as a black American woman uncomfortable in South Africa in an office with predominantly white Africans? Not necessarily a black South African person, but a black U.S. person." The CEO also described possible conflicts that have not yet, but could occur.

> These are the potential possible conflicts that you could imagine could occur. Just recognize them all and realize, again, we're on the same team, we're working on the same mission and you've got to address these personally and get over it because I'm not

> going to have that underlying tension because it's just going to distract from all of our jobs.

The executives were asked what they struggle with. Their answers included interpersonal relations and personalities, interpersonal conflict, growth, and not enough employees to do the job. C5 asked "Have we appropriately prioritized relative to anything and everything else [we] could be doing, or maybe we should be doing, to have these products to be in the best possible position?" C1 stated, "I'm learning more and more, people's behavior out of fear and anxiety can manifest itself as aggression, negativity and turf issues." C3 said, "I would say right now the big struggle is just to get enough smart people doing this work."

C3 effectively explained the true struggles all employees at Company C face.

> We struggle. We are struggling with-- the smartest minds in the field and, certainly, in [our area of] science, they all say they think we are doing the right thing, but we struggle. We do not know. There is no [product]. There is nothing that prevents [the disease]. We do not know. So we struggle really profoundly with -- are the dinners that I have given up worth it?

Although she asks whether the missed dinners are worth it, she is profoundly mission-driven and wants very much for the company to succeed.

Risk. The senior executives all described their work in terms of risk, but the specific risks they mentioned varied. C1 discussed her lack of business experience as not as critical as her ability to understand what the risks are. "So I don't have to know the business side. I have to understand enough of what the risks are to be able to weigh in on risk management, but I don't have to be an expert, and I can't force myself to like business."

C1 also described scientists as being risk averse.

> Scientists in general, at least the drug development folks that we've got around us, seem to be very risk averse. It's not to say they're not mission driven, but I believe there are risks to not doing things fast enough. I think it's how you do the risk-benefit calculation. People who are scientists are looking at the risk-benefit calculation in a much narrower context.

C1 adamantly stated, however, “I won’t compromise on risk to the woman.”

C2 discussed her personal risk as a manager regarding her responsibilities for managing and developing her employees. “I’m taking the risk. But I also realized there is no one [than myself] that can be more successful and is more equipped to do the job.” Although the disease that Company C is researching is epidemic in developing countries, it is also a growing problem in developed nations. C3 talked about risk factors associated with the disease. “The epidemiological data and the social science data said the epidemic is moving into married women, generalizing into the populations in the developing world; poverty is a risk factor; social inequity is a risk factor.”

Previously in this chapter, political problems and social upheaval were discussed. C4 put the political risk very succinctly. “If there’s no clinic to get into[in which to do this product research], then there won’t be any [product], so that’s why the importance is to set up these research centers, half in South Africa and half elsewhere, [to account] for the political risks.”

C5 talked about the risk of failure and development risks. He said that although they may fail, the company is fortunate to not be funded by venture capitalists who are looking for a quick, high monetary return. “We have been fortunate that the donors are not like venture capitalists. They were all willing to tolerate failure if risking that failure potentially leads to getting to some place faster -- faster outcome.” He also talked about the problems in predicting timelines for development. He said that when the scientists do not make the predicted timelines to send the products to the clinic, it can be demoralizing for the clinicians.

There is also the issue of the disconnect leading to a lot of reductions in enthusiasm. Sometime, clinical people [who are managing the clinical trials] think they are going to get a

product on a certain date, 10 things go wrong; the date is pushed. They did not, going into the situation, fully understand where each of the risks were.

C5 suggested that having dedicated project management for each of the products can help lessen the risks.

> I see project management, especially for something as complicated as this, as being far more relevant to your overall product development goals. With R&D running as fast as it can and clinical running as fast as it can, [we need a] central function that knows enough about clinical and R&D to look out for risks for the organizations, help identify efficiencies and then serve as an overall tracker of an integrated timeline.

Success. Success to Company C is accomplishing its mission. C4 stated that "Nonprofits are successful vis-à-vis their mission and this mission is very focused." When executives at Company C discuss the mission of the organization, it was with the same zeal that other companies talk about their revenue-based success. C3 frankly stated, "We need a product and we need it now. Obviously, we would like a safe and effective [product] that was cheap. That is success for us in the next four years."

Success itself was often talked about in more low-key ways, such as in overall enjoyment of their work. C1 talked about enjoying the science side of Company C more than the business. She was advised, though, not to completely give up science. "It's in your DNA, the science, the love of this is in your DNA. It's all kind of identifying a senior management team that you can all work with, but don't try to let it go because it's what makes you successful." C1 added that if she were to give up science, "it will not create a mood for success." C2 also talked about success in terms of enjoyment and fun.

> That is for me extremely important that the team must have fun while they work. Because we are working in a day-to-day changing environment and at a really fast pace, and it is important that I as a leader spend time with every team member because everyone cannot adapt to change as far as anyone else. And I'm fortunate I'm aware that the team can only be successful if the last one also adapts.

Success to C2 is related to the extent to which her co-workers and colleagues can also enjoy that same success. C2 stated that "There is no way that I can run the department successfully unless everyone is successful." C2 described the pleasure she has in developing her employees.

> Personally, success is for me to see my people grow and get a job well done. I'm not a person that relies on feedback to feel successful. For me, it is really to put your goals out there and to work closely with a team and to look back and say, it is a job well done.

C2 talked about the need to feel challenged.

> If I feel at once that I cannot contribute to the team to be more successful, I need to move on. It is very important for me that I must feel I can contribute successfully to a team and not just moving papers around and looking busy. I need to really be able to be innovative. By that I'm saying if everything is just working well, we have made a success.

C3 described how having a successful clinical trial in Africa would constitute a personal success.

> Success to me would look like being able to pull off the trial. My career will come totally full circle to the girls that I taught high school to in Central Africa when I was a Peace Corps volunteer. That would be, for me, really great."

C5 said Company C has been successful in three specific areas: raising money, convincing pharmaceutical organizations to donate drug compounds for research, and redistributing some of the resources that Company C has received in funding to other organizations. C5 said the company has been highly successful in convincing pharmaceutical organizations to contribute compounds or expertise. Company C "has been successful at engaging pharma either through the contribution of compounds or other expertise and capability like site development in the developing world or regulatory assistance." C5 also described the CEO as being highly successful at raising money. "If you look at the successes, the raising of the money, clearly, [the CEO] has been a very good representative to the cause."

As described earlier, C5 is concerned about the lack of drug development expertise and worries that this may affect the overall success of the organization. “We lack at the top anyone who has successfully developed a drug through the complete regulatory licensure process.” He stated that there needs to be more experienced people brought in at the senior level who better understand how to develop the products.

> I think [the field is a] very, very tough business, and for a long time I thought [company C] was the best way or chance. I do not think that is true now. I think you need significant change here for it to be ultimately successful.

C6 also believes that more experienced leadership is needed, especially for getting a drug through internationally based clinical trials and into production, in addition to the existing CEO.

> The leadership that is in place now -- it certainly needs some additions because the job would change. [The CEO] is a quick study. She can pick up on the details of whatever she needs to present to the investors, the donors in this case. If she has smart people working for her, she knows how to let them run and do their job. So if [Company C] were successful and it became a manufacturer and a distribution company, it would need people in charge of those functions, that could themselves probably run a company but she continue to be the front-end.

Possibility of failure. Concerns of company failure are related to whether the products will work. C4 described a series of problems in the development of the products.

> On the science side, we have one roadblock after another. There’s no clear path to how we’re going to end up with a product. It’s been a several-year series of failures and disappointments around [one of our products]. So we’re ending up having to build our own manufacturing plant.

C5 said

> It is very common for drugs to fail in terms of efficacy in their trial, but not too far down in terms of common occurrence is the fact that drugs fail for reasons related to the drug product itself - either the manufacturing process has not been appropriately validated or the analytical methods have not been appropriately validated.

However, C6 thinks if the products work, the organization will be successful. “I think [Company C] will be successful if the science is viable. So that is the big question: Does it work? Who knows, but I think the execution on it has been pretty good and no more ‘bumpy’ than anybody would expect.”

Summary of Findings

Company C is a non-profit product development partnership that is highly mission oriented and undergoing very fast growth. Five current employees and the former Chief Science Officer were interviewed. Major themes that emerged include, leadership, mission orientation, science-business interaction, teams, challenges, risk and success and failure. The overarching theme, however, was their mission orientation toward disease prevention.

Consultant Interviews

I consulted with three experts in the field of technical organization management who have direct experience with scientist/founder leaders at biopharmaceutical companies. Consultant 1 is an executive coach, consultant 2 is a venture capitalist and consultant 3 is himself a scientist/founder leader and an advisor to venture capitalists who has begun a consulting practice.

Consultant 1

Consultant 1 works as an executive coach to leaders and provides leadership team development in biotechnology and other industries. He has coached several biotechnology leaders, including a number who are scientist/founders. Consultant 1 has 25 years of experience in human resources and has dealt in people-related issues while working in corporations serving commercial organizations, government contractors, the U.S. Government, and not-for-profit organizations. He holds a master’s degree in business administration and is a Professional

Credentialed Coach (PCC), with a certificate in Leadership Coaching from Georgetown University and a certificate in Organization Development from NTL Institute.

Sustained leadership requires effort. Consultant 1 believes leadership "can be a learned trait." He stated that sometimes leadership is learned "by definite intention to do so" and other times it happens circumstantially. He said there is a distinction between leading a company, which he describes as "sustained leadership…whereas some people can rise to lead under a circumstance for a condition but they could not or would not want to sustain that." Consultant 1 said that some scientist/founders are able to lead for a time but may need to step aside and bring a different type of leader for the company to continue to be successful. He believes that for many scientist/founders it makes more sense that they become a technical advisor at some point in the organization's growth, or "a leader in technology or science versus a leader in leading the organization." Consultant 1 questions how satisfied even successful scientist/founders are and wonders how many might have chosen something other than leading a company.

Consultant 1 stated that successful scientist/founders usually consciously choose to learn to be better leaders "and then do so with a lot of effort and continual evaluation of how they are doing." He stated that almost all successful scientist/founders do so with help such as long-term coaching or some other type of information gathering, such as a 360 degree assessment. Consultant 1 said that there are many different types of coaching that the successful leader may require, such as direct coaching from a trained expert, or they may require "consulting coaching, in which an expert in the field helps the leader to understand dimensions of leadership or a more specific dimension like financial matters." He also stated that that there are forms of ad hoc mentoring. Mainly, Consultant 1 said scientist/founders must initiate "a conscious action at all

times to be a successful leader: 'I'm consciously seeking out ways to become better at my job as head of this organization.'"

What leaders need to learn. Consultant 1 said that although leaders often have a lot to learn, they especially need to learn humility. He stated that scientist/founders may attempt to "add too much value" to the organization by sharing their scientific expertise with subordinates in some circumstances. If a scientist/founder is an expert in a specific scientific area, he or she may be tempted to "pick apart" the chief scientist's idea and explain how something might be done better, "even when it will not make much, if any, difference in the final analysis." Consultant 1 said that this kind of micro-management is "almost inevitable at some point because they grew up as a scientist who is going to be picky. Their intention for the most part is to dig deeper, to find other things, find flaws by their training/upbringing and so when you do that, it can be very de-motivating." The result of this micromanagement can be subordinates who become disinclined to extend their own viewpoints because they may be invalidated by the leader.

Transitions and career anchors. Consultant 1 said that all people have "career anchors" that are the basis for what we are most interested in.

> Many founder-leaders' interests truly lie in science, versus successful leaders who say, 'You know what? I'm interested in science but I am getting farther and farther from the science. I probably better leave this to the guys who know more about science.' As CEO you should not be doing science. If you are doing science, there is something wrong.

According to consultant 1 there are 10 types of career anchors (Schein, 1990). He said,

> We all have one that we are drawn to, meaning that this holds the most meaning and value for me and my working life. And, all other things equal, I would not give this up." We cannot always work in areas that are our career anchor. For instance, lifestyle is one of the career anchors, but you may have to work longer hours or a different type of job than you may want to support your family. "But as soon as you can, you might take a part-time job and stay home more with the kids or whatever it is about lifestyle that interests, or draws you.

Consultant 1 stated that most scientists' anchor is technical functional.

> That means that you are most energized by the technical issues of a situation in a work relationship. And so if you do technical in your job just 10 percent and you do general managerial 90 percent, you wouldn't be happy. And you would not likely do as well or stay in that job because you would not be happy. Because if you are not happy with your job, it is not usually the case that this is the best job for you.

Scientist/founders' career anchor is most likely technical functional, followed by entrepreneurial creativity, although consultant 1 admits he does not have empirical data to support this.

> Those are probably the guys who are more drawn towards starting their own company. I do not think there would be very many, if any, frankly, scientists who have a general managerial anchor, which means I want to manage people and products and systems but not be involved in the technology. Because if they were more drawn to general managers they would have gone to business school versus getting a PhD in science.

Scientists who successfully lead biopharmaceutical companies are successful because they have made a conscious decision to do so. They "have seen the trappings of what a CEO can bring" and liked it. They may like "meeting important people," presenting "a scientific case to the investor community" and the money and "prestige it brings." Consultant 1 argues, though, that what the scientist really loves is the laboratory.

What makes scientist/founders successful? Consultant 1 stated that successful scientist/founders become successful partly because they seek help to do things differently. He stated that scientist/founders who are successful have either learned to evolve and change or "they were lucky." Successful leaders learn that success "is not all about science. It is about the person." He stated that scientists may have to give up some of the science to be "successful in the business environment."

What advice would you give? When asked what advice he would give to a scientist considering starting his or her own organization, Consultant 1 said he would talk to them about

being sure they were clear on what running a company would entail and to ask themselves, will that sustain you? will that make you happy? If it does not, how will you deal with that?" Consultant 1 said he would also ask them whether their ego was strong enough that they could "step aside". Leaders should look ahead to how long they want to stay with the organization. They should ask themselves whether they have enough of an entrepreneurial spirit to start the company and then step aside and move on to the next project. Consultant 1 suggested that very few scientists actually go through this mental process before starting a business. He suggested scientists should ask other people in the industry in order to "get some other data points; talk to guys who are successful or peers and ask, 'What did you learn? What would you do differently?'"

Consultant 1's final advice is that scientists must realize they need to accept imperfection in themselves. Scientists should "just try and be open to the fact that you do not have to be perfect; you will not be perfect. And be able to admit mistakes and seek help from others through this journey." He felt that the successful scientist/founder leader must be capable of growing and changing.

Consultant 1 summary. Consultant 1 pointed out that sustained leadership requires effort and a determination to grow and adapt to changing leadership requirements as the organization itself grows and changes. He said that scientific founder/leaders need to learn humility and be careful to not offer too much scientific advice that may be de-motivating or could be construed as criticism. Consultant 1 pointed out that according to Schein (1990), all people have one of ten types of career anchors in which they feel most comfortable. He suspects that most scientist/founders' career anchors are likely to be technical-functional, followed by entrepreneurial. Leading an organization out of the entrepreneurial stage requires management

skills the scientist/founder may not possess and may require responsibilities the founder may not enjoy. Scientist/founders are more likely to be successful if they seek out advice and support from either professional coaches or someone who has experience in leading successful organizations. Finally, he would urge scientist/founders to admit mistakes and to not expect themselves to be perfect.

Consultant 2

Consultant 2 is a venture capitalist (VC) with a master's degree in business administration from Harvard Business School. He is currently chair of the investment committee of an equity partnership and a director of a number of its portfolio companies. He is a governor and treasurer of a state Academy of Science and a professor at Yale University. He was previously a managing director of a major investment firm and president of a major leveraged fund group, a managing director of a Wall Street investment firm, and a managing director and chief financial officer of at another major firm.

What does success mean? Consultant 2 defined success in several ways. He said that "Ultimately, it is producing a drug that successfully treats patients and generates a return on capital for investors." However, he said that prior to generating revenue, the definition of success changes with viewer's perspective. He said that "from an investor's standpoint, [success] would be whether or not liquidity and a return on capital are generated." Consultant 2 said that "most scientific founders at one point are motivated by seeing their intellectual efforts manifest in drugs that treat patients." He added that sometimes scientist/founders get distracted and "start focusing on their own net worth, which is not unreasonable. Some of them, unfortunately, focus on the sides of the organization they get to run and start to measure success based on their authority."

Another form of success from a VC's perspective would be for the company "to have drugs in Phase II or Phase III with a fairly rich pipeline before that."

Many leaders don't stay the distance. Consultant 2 said many scientist/founders "do not go the full distance of staying with the project - leadership in a CEO position through the point of late Phase II or early Phase III."

Many VCs are leery of "funding a first time scientist/founder because the inexperience and idiosyncrasies of those people make the outlook very difficult for those companies." For scientist/founders to successfully attract institutional funding usually requires that they have founded other companies previously. Consultant 2 said that because scientist/founders are bright, they are capable of learning. "They develop a greater sensitivity to what the commercial exigencies are of making a drug." He pointed out that usually scientist/founders have a commercial counterpart when they start the company. "They have a commercial alter-ego. That is extremely important. They will either be inside the company, on their board, or good friends."

Consultant 2 said that even successful scientist/founders may begin to cede CEO control as the company starts "leaving the early research stage around the point of designation of a clinical candidate or pre-clinical development, certainly, on the cusp of clinical development." He believes this is because "the demands of clinical development are temperamentally and organizationally very different from early research." He pointed out that those scientist/founders with an MD/PhD may "last longer because their sensitivities to the demands of the clinic -- in working at hospitals and FDA filings -- are going to be different." He said though, that once the company has products in clinical trials, the changing demands of leadership may not be as enjoyable as the scientist/founder may have originally thought and the scientist/founder may

want someone else to take over leadership. “Their passion is really much on the research side, as opposed to dealing with the regulatory problems.”

Scientist/founders may also “be ill-suited” to being CEO if the company goes public or partners with a pharmaceutical company. If the company goes public, the time demand of the CEO changes dramatically and they then have to spend much of their time traveling and “dealing with institutional investors.” The investment community or their board may not want the CEO in this role, or the CEO may simply be “miserable.” At this point, the scientist/founder may voluntarily step aside. If the company is partnering or is acquired by a large pharmaceutical company the CEO may “just not invited to be in partnership.”

Passion versus control. Consultant 2 said that much of the early conversations he has had with scientist/founders are to help them “understand the distinction between the passion to see something realized as a drug and the need to be in control, because much of being in control of a biotech company involves running processes that are alien” to the leaders. He reiterated that scientists are very bright and capable of learning “and some of them are more self-aware than others. Most of them start out confident enough that they can do anything.” Consultant 2 believes that an important part of his job is to make it easy for the scientist to “acknowledge that they do not want to do something so that they can gracefully step aside without a ‘fight.’” Stepping aside is very difficult for many scientists because they can be very passionate and committed to seeing the drug through development. As Consultant 2 pointed out,

> A lot of these guys have never gotten a “B” in their life and if they start keeping score when measuring themselves against their ability to retain control in the commercial enterprise, that can be a disaster. So it has to be clear to them that success does not need to be measured in whether they continue to be called the CEO, but rather by the way that their projects continue and whether they are in good hands.

Another important component for the scientist/founder is monetary. The scientist/founder usually ends up with two to four percent of the company. There tends to be a high degree of correlation between seniority in a company and the level of ownership. According to Consultant 2 "At one point, if the VC is too greedy or too insensitive, they will create a dynamic where the CEO has very strong economic reasons for not wanting to step aside." The VC should try to make stepping aside financially attractive in addition to not damaging the CEO's ego. The VC should also help the CEO "find a really good partner, somebody who can succeed them or work with them and ultimately succeed them, is time consuming but important." The CEO can become the chief scientific officer (CSO) or chief medical officer (CMO) for a company. Consultant 2 said the CEO transitioning to the CMO is less common because the "CMO responsibilities usually emerge at a later stage." The CEO may more likely become the CSO or "they step out of the company, go back to their academic labs and stay scientist/founders on the board." Consultant 2 stated that there are a limited number of scientist/founder CEO's

> who become students of being a CEO and learn how to lead a company. But by the time they are in preclinical and clinical development, they will find themselves spending less and less of their time on research and the sort of management issues in a laboratory that got them into the company in the first place. I would be surprised if they find themselves spending more than five to 10 percent of their time actually interacting with their research people.

Of the scientist/founders that Consultant 2 has helped fund, more than a few have been able to maintain their position as CEO and continue to lead the company successfully. This is because he has consciously supported the CEO when he believes they are able to succeed, or the CEO has stated they do not intend to remain CEO.

> I consider them a success, too. Among the companies with which I am currently involved, two thirds come to mind now who have worked out very well. A reasonable number have stayed on as CEOs and the ones who have not have quite consciously moved themselves out of this. And they have been in control of that process and done it with the full support and awareness of their board.

Consultant 2 also mentioned one way for scientist/founders to gracefully exit is through the use of executive coaches who help the CEO remain "self-aware through this process. So they do not start perceiving this as a 'B' or 'C'; they actually see it as liberating."

VC support. VCs primarily support to the CEO and the company with money. According to Consultant 2, some VCs as a matter of policy "will not fund first time scientist/founders because the aggravation that comes with that is just enormously high." He gave an example where against his better judgment he and his colleagues "spent six to nine months working with the guy and ultimately had over $30 million worth of funding arranged with an excellent group of very experienced venture capital." The VCs wanted to retain the right to replace the CEO if they felt it necessary. The scientist who was trying to have the VC fund his new company would not agree to be replaced. As a result, the scientist may now not be able to find funding from other VCs.

> It is quite remarkable. He has many, many years of time invested in this and now, rather than setting himself up for success in developing a drug, he is just alienating the sources of capital who can fund it and help him. It cost hundreds of thousands of dollars of real money and opportunity times for firms to commit to this sort of thing. When you walk away from them, it is a very small community, so I just do not know what he thinks he is doing.

What VCs look for. When VCs are deciding whether to invest in an opportunity, the first thing they look for is "a good project." He also said that the scientist/founder must be "self-aware. They have to understand having other very capable people around them with diverse abilities." One way he can tell a scientist is self aware is "if they run a lab where everybody is obviously intellectually subservient and they cannot take advice, they are not willing to learn. Those are all bad indicators." Other bad indicators are if the scientist appears to

> obviously have contempt for the source of their funding and they consider it just an encumbrance or they consider the day-to-day needs of running an organization and taking

> care of people as a burden, those are bad signs. If they are not responsive for the need to plan and to budget and to adhere to those sorts of things, those are a problem. You can tell pretty quickly whether there is going to be a problem.

Examples of success. Consultant 2 gave examples of three companies he has helped fund with a scientist/founder who have been successful. Interestingly, none of the three scientist/founders had previous experience starting a company. He mentioned one public company with a medical doctorate and a PhD founder and CEO. The company's first drugs did are not "sufficiently efficacious" to be made into products. However, they have a second generation of products in a different disease area in clinical development that appear promising. The scientist/founder "quite consciously moved himself out of that position over the past year, elevating the person who had been his commercial alter-ego in the company as the new CEO." The founder has become the chairman. The company raised $100 million in its public offering and is considered a success because it has a rich pipeline. However, because it does not yet have a product, it is not a success from the investor's and the patient's standpoint. The CV believes the founder

> experienced a very successful life cycle at that company and was a student of how to be a CEO and built an organization of almost 150 people, spending almost $70 or $80 million a year. So it is a very serious business, and I think his experience there was quite successful.

Consultant 2 said that the scientist/founder would have a high likelihood of being funded if he wanted to start another company if the science was strong. "His references from his board would be extremely strong and the people on his board are serious institutional investors." Consultant 2 believes that this founder could have continued as CEO, but he reached a point where he did not want to anymore. "He had also been at it for over 10 years and I think he sensibly thought that 10 years was a long time to spend at any one thing."

Consultant 2 gave another example of a successful company with a scientist/founder from academia who "very consciously engineered his succession in two phases and then moved out of the company and back into an academic role as the company progressed further and further into the clinic."

A third example is a company based out of a university that has a highly successful product and another with disappointing results. The scientist/founder is "still CEO of that company and has taken it through all sorts of difficult times." A fourth example is of a successful company where the scientist/founder CEO who understood what leadership at various stages meant and he still wanted to run the company. Consultant 2 said "it is also one of the happiest companies I know. He makes hard decisions, but he has managed to maintain a wonderful tone in the company. They have not had any crushing setback, yet, so we will see what happens then."

Traits of a successful scientist/founder leader. Consultant 2 described traits of the CEO in the four examples cited above. All four "were self-aware; understood what the needs of building one of these companies were; entered into sensible, thoughtful partnerships with their investors, and took advice. They were all very strong-willed people who also built very strong teams around them." Additionally, they were all adaptable to the changing needs of the organization. Another trait Consultant 2 notices in scientists as clients, is that they are very bright and as such, they tend to want to be creative at times when it is not necessary.

> The brighter they are, the more original they think they should be on forms and transactions. That is not how business is done. And the ones that do not get that often get themselves quite seriously stalled, and the ones that do get it are very, very effective.

Consultant 2 stressed the importance of potential founders being very aware of the "audiences they are dealing with" and that they do a lot of thinking and researching before they

attempt to start a company. “So much of commercial leadership at a CEO level is not about responding to problems but anticipating them.” He said that many will fail if they try to be too “original” in their thinking and do not obtain information up front. “The ones who have been more successful, in my experience, have done more homework.” He went on to say that most of the successful founders have “also established a very sensible relationship with somebody who is experienced in this business and they trust them.”

Consultant 2 said that sometimes it is easy to predict if a CEO will not succeed because they lack obvious important skills. “If they lack communication skills or they lack vision or they lack tolerance for adversity and these sorts of standard measures that you need is leader they are highly likely to fail.”

Transitions of leadership. Consultant 2 described the problem many CEOs have with transitions in the growth of the company. “I think there is a kind of leadership that sometimes makes a laboratory great and is quite collaborative.” He said that once a company moves into a development phase “it is very typical that, particularly the clinical development, staff gets very frustrated by laboratory-type decision-making process because they really do want clarity.” He said that

> without exception, every biotech company with which I’m involved has to go through this change or this transition or melding of this sort of leadership issue where you have a CEO who is used to running a lab full of people who has to learn how to partition this decision-making process.

Consultant 2 said he has seen this example many times and says it is not fatal. He said that the people who are responsible for running the clinical trials are the ones most frustrated by a collaborative decision making style. He said research scientists would probably prefer a collaborative style, because that is what they are used to. “The solution is not necessarily for the CEO to become a dictator, but it is often for them to recognize that one side of the business

requires one kind of decision making and another side requires a different one." Consultant 2 said a similar transition happens in industries other than biotechnology, particularly with research engineers. "The closer they are to the research end, they will keep their toys on the table and keep doing prototypes as opposed to saying we have to lock this down."

Tension between science and business. Consultant 2 described the tension that can exist between scientists and business people as mainly from

> someone who is really naïve who have not been through developing technologies before, so the business guys might get a little hysterical or the science people think that they are tone deaf but in companies with experienced boards, I do not really see that as a schism.

Our interview concluded with Consultant 2 referring back to the example of the company where the employees are happy and the culture is extremely positive. He said the CEO has done an excellent job of surrounding himself with experienced people in clinical development, project management and commercialization. The CEO may have even

> over-invested in people like that but the beauty is that skilled people have never been a constraint on how his company has grown. He has not lacked for the strength in sort of the executive team to handle whatever challenge they have confronted.

In other words, there is very little tension between scientists and business people, in the company, because the leadership is experienced and understands different styles of leadership.

Consultant 2 summary. Consultant 2 defined success differently depending on perspective. He said from a patient's perspective success is a new treatment for disease; from an investor's perspective success is a return on investment. Consultant 2 said many scientist/founders find they are not suited to leading a company into clinical development and may prefer to either leave the company or take on a different role. Some scientist/founders find they are unable to relinquish control of the organization when investors think they should and this can lead to failure of the company. If a scientist wants to continue to lead they must be

willing to change and adapt their leadership styles to different circumstances. Scientists tend to be smart people and are able to learn to lead if they desire.

VCs look for scientifically sound projects and scientist/founders who are self-aware. Consultant 2 said that VCs can support scientist/founders financially, but VCs look for specific traits that make the VC believe the investment would be sound. These traits include being self-aware, understanding the needs of the organization, the ability to learn and adapt and the ability to build strong teams of experienced individuals. Scientist/founders need to be aware of the audiences with whom they are working when looking for funding and they need to be reflective in their decision to start a company. He also said that they need good communication skills, visionary and have a tolerance for adversity.

Consultant 2 gave examples of four successful organizations with scientist/founders and said most VCs prefer to invest in companies where the scientist has previous experience running a company. He said that scientists can be successful leaders if they learn to adapt their styles to different situations and that some of the tensions between scientists and business people are due to lack of experience of one or the other.

Consultant 3

Consultant 3 has a medical degree from Georgetown University Medical School. He holds a number of patents and is the CEO of a drug development organization. He has been extensively involved with both the formulation and clinical evaluation of several drugs. He has experience with the U.S. Food and Drug Administration and several international world regulatory agencies. He serves a director for multiple life sciences companies representing several institutional investors and is the Senior Scientific Advisor to a not-for-profit drug development organization.

Different definitions of success. According to Consultant 3, many founders do not recognize that their definition of success is not always the same as their investors'. Scientists may believe they want to be profitable, but many founders are actually more concerned about scientific or technical proof–of-concept, and whether or not their idea can actually be developed into a therapeutic, rather than how much money they may potentially make. This consultant said that scientist/founders realize that they must present their idea optimistically to potential investors, but in reality, they may have doubts themselves about the concept's viability. Scientist/founders may not be willing to admit to themselves that they are concerned about their idea's feasibility.

> My definition of success [as an inventor] was actually seeing that the idea worked, and 'work' was defined technically. Even though I always spoke about money, I noticed when [I got a customer,] the weight from my shoulders was lifted. I had to go back and think about why I felt relieved when I got a customer as opposed to [when] I became profitable. And I see that more often than not in scientific founders. In fact, I'm not sure of a case where I have not seen it.

Consultant 3 added that for many scientists, their reputation is more connected to being technically correct than being commercially successful. "What you ask people to bet on is that your idea works. Every VC tells you that the kinds of guys who start companies are often or usually not the same guys who should run companies."

Transitions. Consultant 3 said that different people are better suited to different phases of a company. He said,

> Good founders do actually have a plan or at least of vision of where they need to get to. The emphasis is completely on building as opposed to running, so at some point you transition from a startup to an operating company -- different skill set operating a company than getting it started; it is just not the same thing -- a different way.

This consultant used the analogy of a battle zone where the first troops into a battle are quickly replaced with different soldiers with different skill sets. "It is a different mentality,

different set of rules, completely different infrastructure. When you start a company, you are in a development mode; the company gets going and you are in an operating/sales mode."

For the scientist/founder to help lead the organization to success this consultant believes that they need to either step aside, or, at the very least, bring in the right people to make the transition to different phases. In cases where the scientist/founder has stayed on as the company's leader, it may be because the leader is successful at bringing in the right team. "So those are two different types of staff. It requires a scientific founder that can make that transition." He said that the successful scientist/founder hires people that can help make the transition.

Consultant 3 said that scientists are simply not trained to understand the many different aspects of business, such as "a set of financials." He mentioned a quote by Niels Bohr, the first scientist to demonstrate the location of electrons around the nucleus. "It went something to the effect that the only thing [Bohr felt he] could not understand was accounting." Consultant 3 argues that medical doctors may have an even more difficult time founding a company "because we [physicians] are trained to operate independently. We are not trained to play nice. Largely, people go into medicine is for that independence. When you run a business, you cannot be independent." Life scientists may not fare any better, although this consultant thought academia may be more effective at fostering a team environment compared with a hospital environment, where "it is certainly more of a hierarchy. Depending where in that hierarchy you are -- the higher up you get, the more hermit-like you are allowed to be in many ways."

Consultant 3 suggested training would help scientists to better lead companies. "The real key has been if people would just realize that being generous and not protective of their knowledge is the best way to succeed because, invariably, that's where these guys fall apart." He

said scientists are too concerned about getting credit for their work and "just wanting to be around for the glory and not wanting to give up any control."

Consultant 3 said that in the early stages of the company, the scientist/founder can interact and have daily contact with everyone in the company. As the company grows, it becomes impossible to maintain the same level of contact and people begin to realize they may not be able to stay as connected. "Everyone needs to say to themselves, 'I guess if I'm running a clinic I'm not going to really know what is happening with R&D on a day-to-day basis.'" As the organization grows, people struggle with communication systems. Those scientist/founders who start companies may be uncomfortable with the growth and may prefer to be in a more academic setting.

> You do not like it that something is happening without you. Some people are much better running those kinds of groups than they are in running the more organized groups. And they are just not taught how to run the organized groups. It is a different skill set.

Science business interaction. Consultant 3 said that there is frequently a clash between science and business.

> It is just that the business people want to get the product out the door and the science people want it perfect before it goes out the door. One way of saying that is at some point you have to shoot the engineer. Just get a product out the door realizing that it will go through a number of revisions.

This consultant said conflict can be prevented or resolved with a strong leader who is an adept communicator with the employees. There is a "tendency for people to hold on to the wrong people for too long. If I were to start a new company, I would do it differently than I probably did it the first time, in terms of setting expectations." He said he would work harder to commercialize a product and then perfect it later with new versions. "We need a relatively straight line between what we are doing and revenue because without money coming in from some place, we do not get to make versions 2 and 3." Scientists would accept this better if they

understood early in the process the importance of fast development to generate revenue. Clearly setting expectations is critical, but may be difficult for scientist/founders who themselves may not really accept "what the financiers are telling them. He or she says to themselves, 'I will take your money. I understand you want this out the door, but down deep I know when it is going to be ready.'" This is because scientist/founders' "internal marker of success" is different from the "one that they put down in their business plan."

Consultant 3 said that an important part of training for business people ("MBA types") would be to educate them in understanding the culture of scientists, especially in academics. "In an academic institution all you do to a large degree is work that makes sure you get the next grant. And that almost always has very little to do with coming to an answer or an actionable answer."

Scientists are trained to be curious. This curiosity is not commercially motivated, so, according to this consultant, scientists "do not care unless it has real world impact." He said scientists should be trained to understand that their mindset is often not appropriate to run a company. Business people need to understand scientists' motivators and not focus too heavily on the money aspects.

It is not the reason the person went in that lab, and it is not what their self-worth is based upon. Their self-worth is really based upon recognition by their peers. And that does not come from being in the background when the thing goes to market. They want to be on that podium. So how do you make sure that happens and still have a viable business?

Ego and investors. According to Consultant 3, many scientists do not understand that "giving up control is not necessarily the same as giving up credit if you do it well." Scientists need to also understand that if they fight for too much control with their investors, they may

"invariably end up losing and are taken out of the picture. So what you fought so hard to get is the exact thing that you are guaranteeing you will lose."

Consultant 3 gave an example of an on-going situation where this was happening. The scientist/founder is arguing for more control and is about to lose $30 million in investment money. The consultant said it is because the scientist/founder has "an almost childlike desire to be recognized and pandered to and told how great he or she is. So it is completely self-destructive behavior and the point where every other VC has said, 'This person cannot run the company.'" The scientist/founder would not lose money if he gave up control and would be expected to make as much as if he were still CEO. "The investors ended up walking away from this guy after he made one too many demands. It happens all the time." Even though there was the possibility of a substantial return on investment, the investors are not willing to take a risk on this particular scientist/founder. According to Consultant 3, the investors' attitude was essentially, "Nah, life is too short."

When I asked consultant 3 what he struggles with, his response was "Just playing it out each time." Consultant 3 is not surprised at the range of possibilities of egos in companies with a scientist/founder, but says that even in the example above, a good scientist/founder needs to be "somebody who is really, really solid in themselves." He said the problem with many companies, is the ego of both scientists and business people can interfere with making transitions. He gave an example of in the medical world of a

> perception by docs that business is a lesser calling, which is just complete nonsense, right? There is nothing more important than giving people jobs. But you will get docs who will -- as business people will say, "Well, I just cannot -- someone has to [take care of the] financial stuff. I'm not doing that." And what they are saying is that it is below them.

Consultant 3 said that business people will sometimes "belittle the technological challenges. But if people would get over that one fundamental flaw, [thinking other professions are below them] a lot of these issues we discussed probably would just go away."

Another area VCs will not invest is in family businesses. Consultant 3's first company was one he started with a family member. The VC who first invested in the business had Consultant 3 write into the shareholder agreement "that if there was a disagreement between myself and my [relative] that it would not go to court; it would be arbitrated by him. In retrospect I know exactly what he was doing. Turns out [we] never had a fight like that, but I have seen it in other places."

Consultant 3 summary. As with the other respondents, Consultant 3 described different definitions of success. In particular, he said scientists may be secretly concerned most about proof–of-concept rather than potential revenue opportunities. Investors, of course are concerned about revenue. He said that as the company transitions from a research focus to a development focus, many scientist/founders may find themselves unhappy as CEO, because they must revise their focus from science to the business issues. He said that at this point the scientist should either step aside or bring in others with experience to help make the transition. Successful scientist/founders can be trained to continue to lead the organization, but they must want to do so, or they will not succeed. Conflicts between scientists and business people can be alleviated with a leader who is an adept communicator. Training is important for both scientists and business people to better understand the cultures and motivators for each group. Scientists, in particular, need to understand that giving up control can be beneficial and does not necessarily mean failure. VCs are leery of investing in companies where the ego of the CEO is so great that they find it difficult to give up control of the company. VCs are also generally not interested in

investing in family businesses because of the unique, non-transactional, not-easily-controlled dynamics in such a business environment.

Chapter V: Discussion

Introduction

This chapter presents an interpretation of findings from the case studies as they relate to scholarly leadership research and to the findings from interviews with the expert consultants. In Chapter 2 of this dissertation I described general leadership practices and strategies that many scholars agree are important to successfully lead organizations. The leadership practices described in the literature include articulating a vision and representing the values of the company, creating a learning organization and adapting to challenges, providing strong communication strategies, developing a positive systems culture, creating small wins, and offering different leadership styles as appropropriate to the organization phase in the company's life cycle. Although the leaders in the cases I have researched use many of the strategies, and exhibit many of the practices, recommended by the scholars, three meta-themes consistently emerged from the 20 interviews I conducted. These themes include: 1) transitions and change as they relate to company size and the leadership requirements (adaptability), 2) the leader as a continuous learner, 3) the need for effective inter-organizational communication.

Summary of Findings

The following is a summary of the highlights of the findings from Company A, Company B, Company C and the consultants.

Company A

The case study for Company A was based on interviews with eight employees and aggregated data from a 360 degree assessment of the CEO and published articles about the company. Major themes that emerged from the interviews include decision making, leadership, conflict, change, success and failure, vision, goals, communication, culture, process, and risk.

The CEO's decision-making style was discussed in almost every interview as a major concern. However, the CEO leader follows many of the leadership strategies suggested by scholars. The CEO clearly articulates the vision of the organization, and employees feel he embodies that vision daily as he works to move the company forward. The CEO does not appear to be overly egotistical, and he attempts to adapt and learn new styles of leadership as evidenced by comments from his executive leadership coach. His style is still highly collaborative and he continues to strongly value the opinions of others. He regularly works with an outside executive leadership coach. He has participated in a 360 degree assessment instrument and appears to make many decisions by committee. Although the company has products in clinical trials, the organization as a whole still maintains a highly scientific and research focus rather than having evolved to a product development focus. Two-thirds of the company employees are scientists; however, all senior executives are non-scientists with the exception of the Vice President for Research and Development. The Chief Medical Officer at Company A even defined success differently: as helping patients rather than being financially successful, as defined by the CEO.

There does not appear to be tension, nor does there appear to be high levels of interaction between the scientists and the business people. The lack of tension may be due to the lack of interaction between these groups. Scientists and business people may have different personal motivators, such as a need for recognition of their expertise by scientists and financial rewards by business people.

Company A has transitioned to a clinical development organization with drug studies being conducted in humans. The clinical staff has expressed feelings of frustration as a result of the highly collaborative decision-making process, which is more typical of scientific and R&D organizations.

Lack of effective communication is a growing problem within the company. The CEO required all senior executives to be more communicative with their staff as part of the yearly personal goals. One executive pointed out that the CEO may be too personally involved in communication when he notified the entire company of news that had already been disseminated. Disjointed communication has led to a sense of disconnected, inefficient communication. There are frustrations and struggles among some of the senior executives. According to some of these staff, the problem may be a communication issue and the CEO may not be entirely aware of the causes of these struggles. Part of the communication problems may stem from a lack of staff organization hierarchy. For example, it was not clear to some of the interviewees that the CEO views the organization as an entire system.

The company is effective at showing staff recognition by celebrating small wins with the employees through the use of awards and other signs of recognition. There does not appear to be a sense of urgency among the senior executives regarding development and commercialization of their key product, but they do seem anxious for the leader to change his style and become more decisive and less vacillating. The CEO is seen by his staff as caring, compassionate, a good role model, and technically accomplished. He has good people skills and is inspiring to employees. He is highly involved in the organization, and despite his struggles with decision making he can be directive, for example when he formally asked all senior executives to participate in the company's research. He also required all senior management to move beyond their personal comfort zones and work harder to communicate with their staff. The CEO does not have prior experience running a company.

Company B

Company B is a large, profitable, and successful biopharmaceutical organization that is a leader in the biotechnology industry. I interviewed four senior executives in the organization. The major themes that emerged included how to succeed, decision making, leadership, failure, change, surviving change, risk, organizational processes, vision, mission and goals, transparency, and conflict. The CEO is regarded as highly decisive and charismatic. Although he expressed genuine concern for his employees and patients, he does not openly express his vision for the company other than one of continued growth. The company appears to be a learning organization and has obviously successfully adapted to challenges. The CEO has adapted his style over time and is much less likely to be viewed as a maverick as he was in the company's early years. The CEO described communication and networking as extremely important to success and does not approve of employees spending too much time with e-mail communication. He vehemently argues that face-to-face interaction is critical.

The leader and senior executives did not mention generating small wins or a sense of urgency as part of the company's success. There appears to be a positive systems culture, but the CEO pointed out that he does not try to influence the culture of the organization's international locations and believes that they should operate autonomously within their own cultural environment. The CEO embodies the story and success of the organization and he regularly visits and talks with employees at all levels. For example, I observed the CEO eating lunch in the company cafeteria and chatting comfortably with an employee who was clearly not a senior executive.

Several executives described leadership as a type of parenting, but the CEO described himself as being emotionally neutral and not allowing himself to become too involved with the

people with whom he works. The CEO appears to care about his employees and especially the patients who use the company's therapeutic drugs. The CEO does not overtly appear compassionate, but he is a good role model, inspires his employees, and has good management and people skills. He is technically accomplished and promotes a high level of communication between people and departments. He had no prior experience running a company before he founded Company B.

Company B, from multiple perspectives, is highly successful. It generates a profit and produces effective drugs for patients. The leadership within the organization has evolved and successfully transitioned to the changing organization requirements as the company has grown. In addition to concern for patient safety, the concerns expressed most often were how to continue the growth of the organization and maintain the entrepreneurial spirit that has helped the company succeed thus far. The senior leaders of the organization all have backgrounds and experience with major drug companies. When Company B was founded and began to grow, the leaders agreed that they wanted to bring the experiences and lessons learned from the large drug companies into the organization, but they also wanted to leave out the unnecessarily bureaucratic ways of the large, established firms. Company B struggles with how to maintain growth without becoming overly bureaucratic. Part of the success of the organization is a result of the leader's ability to bring in experienced people whom he trusts and to whom he delegates decision-making responsibility. By his own admission, the CEO does not involve himself in the day-to-day running of the organization. In fact, he states that because the company is multi-national he allows the regional leaders to run their part of the organization according to cultural norms and practices of that region. He only involves himself when there is a problem requiring his attention.

Company C

Company C is a fast-growing, non-profit biopharmaceutical organization with a strong mission orientation. The company is a new type of non-profit organization, a product development partnership (PDP) which combines many features of both for-profit and non-profit companies. This hybrid type of organization is new in the past ten years and is the result of an un-met health-care need that for-profit pharmaceutical organizations have not met because of the high cost of drug development. These new organizations combine the results-oriented approach of for-profit companies with the funding sources of more typical non-profit scientifically based research institutes.

I interviewed five senior executives and the former Chief Science Officer at Company C. Major themes that emerged from the interviews and published articles on the company include leadership, mission orientation, science-business interaction, teams, challenges, risk, and success and failure. The predominant theme from speaking with the senior executives is their overwhelming sense of mission. The CEO embodies the mission, and through her actions and words communicates this daily to her employees. The CEO has created a learning organization and she is adapting her leadership style as the company grows. Expert consultants have been hired to provide guidance and support for the CEO, senior executives, and other employees. The company struggles with communication issues because the organization has grown very quickly, from 40 employees to almost 100 employees in less than one year. The CEO has implemented more senior-level meetings with an emphasis on communication between departments. There is a positive systems culture throughout the organization, although there is some tension in the research and development team regarding the senior executives' lack of experience in developing and launching a product. The growth of research and development has not kept pace with the

overall organization and there is general agreement that there is a need for more senior-level employees in that area.

There is a strong sense of urgency at Company C to complete its mission. The CEO shared a story with me and several employees outside of the interview. She described a clock ticking on the wall and said that for every second the clock ticked, another person is infected with the disease the company is trying to prevent. All employees appear to feel an almost desperate sense of urgency as they work long hours. One senior executive poignantly wondered whether they would be successful in their mission and whether all the missed dinners were worth it.

The CEO has done an excellent job of creating a holding environment for the employees. The employees appear to feel appreciated and fairly paid. The CEO is regarded both within and outside the organization as being the voice of prevention of the disease. The CEO views the organization as an entire system and appreciates the value and importance that each functional area within the organization takes on. The leader is seen as caring, compassionate, technically accomplished, a good role model, open to new ways of thinking and problem solving, inspirational to the employees, possessing excellent management and people skills, and highly involved. She has had no prior commercial experience.

Although the CEO does not let her ego prevent her from learning to improve her leadership skills, she struggles with not being overly involved and too directive in the research area. She is in danger of losing the confidence of the researchers because of her lack of experience and expertise in fully developing a product.

Because Company C has experienced such rapid growth, the organization is beginning to suffer from a lack of institutionalized communication processes. Communication requirements

have changed, in particular because the company is multi-national and growing rapidly. This growth has created increasingly difficult communications processes within the organization and between its employees.

The CEO has effectively led the organization from the start-up phase to an organization with products in clinical trials. She is decisive, but in many ways she may be too compassionate and unwilling to make necessary changes in her senior executive staff to move the organization to the next level of product development. The organization is outwardly focused and has been extremely successful in fund-raising, awareness-building, and in obtaining and screening potential products. The clinical group has grown rapidly and the leadership of that group appears to be effective. The research and development team has not grown as quickly and there is growing mistrust and concern over the general lack of product development experience among the senior executives. Almost all leaders within the organization agree that a strong scientist needs to be brought on board who has product development expertise.

Consultants

The three consultants I interviewed had extensive experience working with leaders in biopharmaceuticals and life sciences. All discussed the importance of scientist/founder leaders being adaptable and able to learn. Scientists/founders must make sure they seek the advice and guidance of others in similar situations, such as from those who have started and run biopharmaceutical organizations. Scientists/founders must understand that the role of leader changes over time. And a successful organization needs a leader capable of changing as the organization grows. Some scientists who are successful also have a strong self-image and may be resistant to outside suggestions. These leaders may be reluctant to give up control of the organization to outsiders and, hence, if they are not already skilled and experienced in general

organizational management to lead the company to success, it will have a higher likelihood of failure. Additionally, and importantly, many scientists find they do not actually enjoy the role of leader as the company grows beyond the entrepreneurial stage. This can be particularly true when the company enters a phase where the scientist/founder's job has very little to do with science.

Venture capitalists look for prior experience in the scientist/founders they evaluate for investment. However, many will still invest in companies where the scientist/founder does not have prior experience but where the scientist expresses openness to suggestions and to learning. Venture capitalists often perceive scientists as "smart" and as people who can learn if they are open and willing to do so. This holds for management as well as technical learning.

Requirements for Achieving Success

Based on these research findings I have identified a number of requirements that I believe are important for achieving success for newly emerging biopharmaceutical organizations These requirements center on the leader's ability to continuously learn and adapt to various organization growth stages and organization needs. It appears that before a scientist even begins to establish a new organization it is very important for him or her to have a realistic understanding of the evolving requirements involved in starting and running a biopharmaceutical company. A perception that the initial managerial, commercial, and scientific requirements will remain static may persuade scientists to found organizations that will be at risk of failure as they grow beyond their initial stages. It is extremely important that scientist/founders be willing and able to continuously learn, adapt, and change. Because of the dynamic nature of this industry, scientist/founders need to learn how to suppress their ego and even be willing to give up complete control of the organization. As the company grows from its initial founding, it is very

difficult for the scientist/founders to know all aspects of running a vital organization and they need to surround themselves with experienced people whose opinions they trust and to whom they can delegate responsibility. In addition, running a successful company will require scientist/founders to create an organization with high levels of communication and a culture of learning for all employees.

The Nature of Leadership Styles at Biopharmaceutical Organizations

Greiner (1998) argues that organizations go through five stages of growth that cause a significant change in leadership requirements and structure of the organization. However, Greiner's findings do not go far enough to describe the needs of the biopharmaceutical organization. Based on my research, biopharmaceutical companies evolve differently than other organizations due to the regulated nature of the pharmaceutical industry. They reach key crisis points that result in the requirement for major changes in leadership and structure. For example, early-stage biopharmaceutical organizations with scientist/founders can initially be highly collaborative and entrepreneurial, but as the company grows, the decision-making styles and processes of communication must also change. This need for change is particularly true as biopharmaceutical organizations begin clinical testing of their drug products in humans. As organizations move into the clinical testing phase, the leader now needs to work within a more stringent United States Food and Drug Administration (USFDA)-regulated framework. Prior to human testing, the company is typically more research focused, and a collaborative style is expected and accepted. However, once a protocol for testing in humans has been established, changes can only be made with USFDA approval. Drug development companies require a decisive leader capable of delegating responsibility to expert senior executives in various, but

interrelated, functional areas. At this point in the organization's development, decisions need to be made by the leader that cannot be easily changed due to the greater regulatory oversight.

The step to human clinical trials moves the biopharmaceutical company from a research orientation to a more operational, or product development orientation. Regulatory bodies, such as the USFDA, oversee and regulate all testing in humans and require substantial documentation. Maturing organizations need focused decision making from their scientist/founders regarding testing in humans, but there is also continues to be a need for collaborative leadership in other aspects of the organization. This is one of the paradoxes of leadership in biopharmaceutical companies. Collaborative leadership continues to be critical in areas such as marketing, manufacturing and the regulatory department as they work together to plan for the launch of a new product. This paradoxical challenge involves dealing with the complexity of simultaneously being both a directive and collaborative leader. Biopharmaceutical organizations experience ever-changing leadership needs within the context of "permanent whitewater" (Vaill, 1996). The essence of leaders who are learners and learning organizations is the ability to adapt and adjust as a complex and uncertain environment evolves. This evolution is not a linear process, but one that continuously circles back on itself while continuously moving forward.

Further, successful leaders recognize the requirement for different styles of leadership and decision making within different functional areas of the organization. Researchers, for example, may prefer a collaborative style of decision making whereas clinical and regulatory staff may prefer a more focused, decisive style.

In summary, scientist/founders need to be prepared to adapt their leadership style to the situation. At times leaders need to be collaborative, and at other times they need to be more directive. It is not unusual for scientists in general to have a highly collaborative management

style because they are trained to collaborate and seek the opinion of others. This style of leadership may work well in the early stages of the organization. However, once a company advances its research to the product development stage and begins pre-clinical and clinical trials, a new style of management is often needed. As the product moves from pure R&D to a regulatory environment that requires stringent oversight for testing in human subjects, the organization's managerial framework tends to become more rigid. For example, a Chief Medical Officer (CMO) at a biopharmaceutical organizations cannot accept changes in decisions related to clinical trials, or with commercialization of the product that may conflict or cause confusion with the regulatory requirements of getting a product through the critical USFDA approval process. Mid-stream shifts in business strategy, which may involve multiple organizational functions, can be tolerated early on, but not later on, when the drug begins to be tested in humans. For example, shifts in how, or to whom, the product may be marketed can no longer easily be dealt with as a collaborative decision once a product reaches a certain point. Such mid-stream changes are notoriously difficult to manage once a product moves out of R&D. Leaders of organizations with products in clinical trials need to trust and, in some circumstances, even defer to the opinion of the CMO or other experienced senior leaders. If the CEO is unable to trust or delegate some decisions to senior executives, a conflict may arise and company executives may become frustrated. This requirement does not mean that the CEO must give up all control but there must be staff in place that can be trusted to make the correct decision. There is a need for directive leadership by the CMO and collaborative leadership by the CEO. There is also the reality of the distribution and marketing systems, political and other realities, all of which require a fluid style of leadership by the CEO that enables him or her to be effective with the organization as a whole. Ultimately, when viewed from this perspective, the leadership is

paradoxical. The leader must be simultaneously tough and directive, while at the same time being collaborative and compassionate, consistent and predictable, and adaptable and open to creativity and dissent.

In addition to trusting the guidance of others, leaders need to be passionate and must be part of the process that helps to create a holding environment within their organization. However, they need to be careful not to become too emotionally attached to individual employees, nor should they come to think of themselves as a parent who is responsible for the general well-being of their charges. Such an attitude can make it difficult to fire employees who no longer contribute to the organization, but who may feel like part of the family. The CEO needs be passionate and embody the story of the company and have concern for employees, at the same time they must be detached enough to make non-emotional decisions that are in the best interest of the company. This is another example of the paradoxical nature of leadership in the biopharmaceutical industry.

I recommend for scientist/founders to lead successful biopharmaceutical organizations, they take two important steps. The first is to surround themselves with experts to help guide them in subject areas in which they themselves have limited experience. One way they can do this is through the use of an executive coach who has experience working with other leaders within the industry. Having a confidential coach with whom the leader may discuss concerns and fears may allow the leader to test ideas before implementing them within the organization. Another step leaders can take is to have access to employees or consultants who have prior experience in successful biopharmaceutical organizations. While the leader needs to be decisive, he or she also needs to understand when to accept the guidance of others and when to defer to other’s expertise.

Often, scientist/founders have difficulty relinquishing control and trusting the judgment of others. If the leader can understand that the success of the organization depends on the leader's ability to make strategic decisions that almost necessarily require input from others who have had prior success then the leader may be more likely to accept advice from others.

Communication

As companies evolve and change, so must their leaders. This adaptation requires that leaders ensure communication processes are in place as these changes transform the organization over time. There will always be a need for high-level, regular communication to decrease fear and increase trust and synergy among employees. However, as the company evolves, informal communication becomes less effective and more formal processes need to be established. The organization's leadership must adapt to these changing requirements. As the leader learns to delegate more, some employees may begin to feel they are losing responsibility, and worry that they are being left out of the process. New forms of communication are required so that those who are left out of some decision processes do not become fearful, confused, or insecure. For the company to be successful, the CEO needs to make sure increased levels and methods of communication are in place. These processes do not need to include direct communication from the CEO to all employees, but employees need to feel that the voice and values of the leader are communicated. If the leader is not able to adapt to the leadership styles required of this next phase, either the organization will flounder, or the leader may be replaced. New styles of electronic communication common to employees under 30, such as text messaging and videoconferencing, may help with communication. As the under 30 year old generation moves into leadership positions, these newer forms of communication will likely become commonplace.

As companies become global and geographically and culturally dispersed, communication issues can become an even greater concern. Geographic distance can increase the need for more communication to help prevent fear and mistrust. This communication can be accomplished in several ways but it must be consistent, expected, and carried out at all levels of the organization. Increased communication will promote trust and better working relationships both intra- and inter-departmentally, and across boundaries. Although face-to-face meetings are encouraged, with such vast distances between groups within the same organizations, electronic communication will become even more important. New technologies that use video-conferencing and other forms of communication between people across distances are increasingly required to build successful organizations. Other, more traditional examples of processes that increase levels of communication might include establishing regular formal meetings, or emails that explain higher level decisions and changes. In addition, the leader needs to create an environment that encourages informal meetings and a company-wide culture of knowledge sharing.

Employee Development

To be successful, biopharmaceutical companies, like all successful organizations, will need to develop and reinforce a culture that empowers mid-level employees and enables them to feel a sense of opportunity and belief that they are part of a long-term venture. Programs should be established to train younger executives in order to cultivate new potential leaders in the company. The culture within the organization will need to be instilled with a sense of opportunity and belief in the organization as a long-term, valuable venture. Communication of the essence and culture of the organization will need to be carried out under the guiding principles created through the leadership of the scientist/founder. These principles will need to be

articulated and embedded within the culture so it will continue after the leader is gone. The company may not need to have an articulated mission statement to be successful, but a common understanding of the vision and goals of the organization is critical. Articulating the vision of the organization can be communicated directly by the leader when the company is small, but as it grows, other means of ensuring that employees at all levels understand the culture and mission of the company must be established. Slogans on the walls are only valuable if they reflect a genuine culture of what the company is in business for. If the business does not continually reinforce slogans with actions and tangible evidence of its vision, culture and value, then it may come across as disingenuous.

Business leaders understand that scientists are frequently motivated by factors other than money, such as peer recognition, job satisfaction, environment, or scientific challenges. Scientists, on the other hand, need to understand that without a business focus, their discoveries may never be fully developed. Although each group may think they fully grasp these differences, their behavior and actions suggest they have not always understood how these differences can adversely affect an organization. Training is needed at all levels of the organization to help communicate across the cultural divides between science and business and to help ensure an increase in effective cross-departmental communication. Training should center on the fact that while both groups generally share similar goals for the organization, there is a need to view the company as a whole, with a systems view of the company. Without such a holistic systems perspective it will be difficult for the company to meet its goals and succeed.

Conclusion

Based on my observations of the three organizations, interviews with their leaders and with consultants, and from the literature, I have concluded that these biopharmaceutical

companies require leaders who are able to continually learn and adapt to the continuous change of permanent organizational whitewater likely to be present as technology organizations mature and develop (Heifetz, 1994; Vaill, 1996). This ability to continuously learn and adapt is the single most important requirement to lead biopharmaceutical companies to success. Without such a perspective, the leader and the organization will likely fail. To continuously learn, however, leaders must often suppress their own egos and relinquish control. Further, leaders need to embody the story and the vision of the organization. Part of that vision should include creating a learning organization where all employees are encouraged and expected to learn continuously (Bennis & Nanus, 1997; Gardner, 1995; Senge, 1990; Vaill, 1996). Such a learning organization should support and give confidence to employees so they will take on leadership roles within their own jobs (Wergin, 2007).

Based on the results of this study, a number of important attributes are required for establishing a learning organization that deal with the paradoxical nature of leading biopharmaceutical companies in the 21st century. First, the leader should be a visionary manager who is able to consistently articulate his or her vision throughout the organization. Second, the leader needs to be a strategic decision-maker and be flexible enough to allow the strategic vision to adjust to the culture and the environment. Third, the leader needs to be able to communicate effectively and create an organization where communication flows efficiently at all levels. Such communication can be extremely difficult in fast-growing organizations where effective communication is needed across cultural, geographic, or functional boundaries. Fourth, the leader needs to recognize that clear cultural differences exist between functional groups. The leader must not give in to the common temptation among both scientists and business people to downplay the importance of these differences. Within the organization, cultural differences need

to be respected, whether they are between people from different countries or people with different functional backgrounds, such as science and business. Finally, organizational leaders need to empower their employees at all levels to make strategic decisions; but at the same time, the leader needs to know which decisions must be retained as his or her sole responsibility.

A Final Thought: Special Challenges Facing Biopharmaceutical Leaders

To be successful, scientist/founder leaders of biopharmaceutical companies face significantly different challenges and experience different life practices when compared with leaders of other businesses. These differences include the manner in which biopharmaceutical leaders have to continuously adapt and learn for their companies to be successful and the communication challenges that emanate from the different cultural worlds of scientists and business people—e.g., the different styles of social interaction and definitions of success. A more subtle, but perhaps even more compelling, difference exists as well. Leaders of biopharmaceutical organizations must balance the enormous financial pressures, concerns and risk with the urgency of saving human lives. The biopharmaceutical industry is unique in this regard. There is very little middle ground in this industry where organizations can grow slowly and organically. At specific growth milestones, every organization must commit to success by investing in the infrastructure, staff, talent, and resources required to make it through clinical trials and into commercial production. Product development can cost almost $1 billion for a single commercialized therapy.

For the most part, scientist/founders' prior experience tends to come from the research laboratory. And, leading a biopharmaceutical organization is very different than running a research laboratory or even other types of business. A research laboratory involves leading in a collegial atmosphere with staff members similarly trained in scientific research where definitions

of success are determined by peers rather than by the market and the development of approved drugs that lead to curing people. Hence, the leadership needs of a research laboratory do not change over time as rapidly as they may in business situations. The skills required of biopharmaceutical company leaders are different from other businesses. Not only are biopharmaceutical companies market and revenue driven, the leaders are also expected to deal with complex and time-consuming regulatory factors and pressures, and with the ethics of testing on human subjects as they find cures for diseases where human lives are at stake. These differences between biopharmaceutical and other organizations can frustrate a highly successful and respected scientist who has become accustomed to doing things their way, to being right and often only used to the styles and leadership needed to run a successful laboratory.

This research has indicated that creating a successful biopharmaceutical company requires the leader to be adaptable and able to change in ways different from other industries as well as from the research laboratory. Business leaders in other industries must learn to adapt to changing organizational needs, but scientist/founders in the biopharmaceutical industry must personally change in more dramatic and fundamental ways. The successful leader must evolve from a scientist, to a scientist leader, to a business leader. Hence, not only must the leader of a biopharmaceutical deal with what Peter Vaill (1996) calls the permanent whitewater common to organizational life, the successful biopharmaceutical leader must also learn to change how he or she perceives the very nature of collegial relationships, how professional success is defined and how the creative urge must be contained. Moreover, this continuous learning and adaptation must be carried out in a context in which the lead time to fully develop a product is much longer than in any other industry. This puts an additional strain on the leader because of the extraordinarily high risk of failure and the enormous financial costs involved. The

scientist/founder, who may have seldom experienced personal or professional failure, finds him or herself in a situation where failure is common.

Because the life scientist leaders often enter the industry with a strong and even primary desire to help humanity by finding cures for illnesses, as well as a desire to be financially successful, they also appear to be motivated differently than other business leaders, including those in other science and technology-driven industries and in those companies with strong ethical concerns. A business leader's appropriate concern with how his or her company impacts the environment, acts in a socially responsible manner or treats employees is very different than an immediate concern for human life and death. The combination of these different personal motivations and the scientist's ego make leading a biopharmaceutical organization more complex than leading other organizations. This complexity is exacerbated by the highly regulated environment in which biopharmaceutical organizations operate as well as the very nature of how these companies evolve and operate.

Scientist/founders may also unnecessarily complicate situations. Their very ability to be highly creative in a scientific endeavor can cause them to be too thoughtful, thorough, and creative when running a business. They may be so accustomed to coming up with novel solutions in their research, that they may fail to realize that business solutions may already exist. Also, too much creativity can engender a level of ambiguity in an organization that must work in a highly regulated environment. The biopharmaceutical industry requires a controlled and sustained focus on preclinical testing and clinical trials over long periods of time. In such an environment the creative urges of the scientist often must be subsumed under the company's managerial needs for producing an approved drug that is marketable. This is not to say that scientist/founders'

creativity is not useful in running their companies, but in some cases their creativity may prevent them from seeing solutions and providing the kind of sustained focus needed for success.

While the results of this qualitative research can not be generalized to any other setting, I believe the three cases do give some clear indication of the complexities and difficulties of leading a successful biopharmaceutical organization. The underlying desire of the life scientist to help humanity juxtaposed to the need to continuously learn and change, understand human nature and leadership, and deal with complicated communication issues in the context of the stringent regulatory requirements and often overwhelming financial considerations, makes leading a biopharmaceutical company not only complex but truly different from leading other organizations. Many scientists may want to succeed in creating and leading biopharmaceutical companies, but because of the personal, financial, and organizational complexities of the business only those few who are capable of continuous adaptation and learning are likely to be successful.

Limitations of Research

This research was exploratory and examined three organizations and their leaders and three outside consultants. More exploratory research is needed that includes additional companies at different stages of growth and success to help determine if these findings are true for other biopharmaceutical companies. Questions arise about company size and type that may affect the transferability of these results. Additional research is needed to explore how PDPs are similar and different to other non-profits and to for-profit organizations. Additional research is needed that includes medium-sized companies and companies that have failed. Further, quantitative research is needed to help identify generalizable themes for biopharmaceutical leaders and organizations.

APPENDIX

Appendix A

Table 1 Leadership Strategies

Author	Vision/ Values	Learning Org/Adaptive Challenge	Communication / Active Listening	Field Theory/Systems Culture/Holding Environment	Disorienting Dilemma/Sense of Urgency	Embody the Story	Goal Alignment	Follower	Motivation	Power (P)/ Empower (E)	Politics	Small Wins	Other
Bennis	X	X	X	X				X					Trust
Bolman	X	X	X	X							X		
Brown	X	X	X			X	X	X	X	X-E	X		
Ciampa											X		
Covey	X						X			X-E			
Dess	X	X	X		X	X	X						Servant
Drath	X		X										
Farkas	X		X			X							Expert
Foster				X	X								
Gardner	X			X		X		X			X		
Geller	X		X			X	X		X				
Gill	X		X			X	X		X				
Greenleaf	X												Servant
Greiner	X	X	X		X			X					
Handy		X			X								
Heifetz	X	X		X	X			X			X		
Hemp	X												
Herrigel		X		X									
Hesse		X			X								
Kanter	X		X	X	X			X	X			X	Accountability
Kellerman	X	X						X		X-E			Limit Tenure
Kotter	X				X				X	X-E		X	
Kouzes	X	X	X	X	X	X	X					X	
Machiavelli								X		X-P	X		Amoral, Theory X
McGregor		X					X		X				Theory X, Y
McKenna										X-P			
Mezirow					X								
Miller	X	X	X			X		X					
O'Toole	X			X									Theory Y
Pascale		X											Facilitator
Priestland		X	X										Confidence
Rausch							X						3Cs
Ready													Share employees
Rooke	X		X	X									
Rost						X							
Ruvolo	X	X	X		X	X				X-E			
Senge	X	X		X		X							
Skipton	X						X						
Vaill		X			X								
Wheatley	X	X	X	X									
TOTAL	24	19	16	12	12	11	9	8	6	6	6	3	

Appendix B: Interview Template

I will begin by expressing appreciation for the leader taking the time to talk with me. I will explain that I anticipate the interview taking approximately 45-60 minutes. I will ask the leader to state for the record if they agree that I will record the conversation and once I remove all identifying information, will use the transcripts and information as part of a case study for my dissertation.

I will then say, approximately:

You have been in the biotech industry for a number of years and began your career as a bench scientist. I am interested in your experience and perceptions of leadership and what you have done to help lead your organization to success. How do you envision your role as the leader of this organization?

Could you talk about your ideas of *leadership*?

How do people engage with each other in the organization?

What does success mean to you regarding this organization?

About 2/3 of the way through the interview, I will ask:

Can you briefly describe your business?

How do you envision your employees interacting within the organization and with clients?

Appendix C: Participant Consent

You have been asked to participate in a research study conducted by, Lynn Johnson Langer a doctoral candidate in the Leadership and Organizational Change program at Antioch University, Yellow Springs, Ohio.

This research involves the study of lived experience, in particular, the experience scientist founders of successful biopharmaceutical organizations.

The study involves, at a minimum, one conversational interview which will be arranged at your convenience and which is expected to last about 1 hour. The interview will be taped. Once the interview has been transcribed, I will share a copy of the transcription for your review. Once the account is written, I will also share a copy of the questionnaire for senior executives in your organization for your review. The total time involved in conversational interviews and follow-up should be no more than 2 hours to 3 hours. If there are any follow-up questions, a second and final interview, with your approval, will be scheduled following the same process.

Your name will be kept confidential, unless and only if you give express permission for me to use your name in my report. You will also have the opportunity to remove any quotations from the transcribed interview. In addition, the tapes and all related research materials including the Informed Consent Forms will be kept in a secure file cabinet and destroyed after the completion of my study. The results from these interviews will be incorporated into my doctoral dissertation.

I hope that through this interview you may develop a greater personal awareness of your own experience as a result of your participation in this research. The risks to you are considered minimal; although unlikely, there is a chance that you may experience some discomfort in the telling of your experiences. If you have any questions regarding your rights as a research participant, please contact Dr. Elizabeth Holloway, Professor of Psychology, Ph.D. in Leadership & Change, Antioch University, eholloway@phd.antioch.edu, 805-898-0114, to discuss your reactions. In addition, you may withdraw from this study at any time (either during or after the interview) without negative consequences. Should you withdraw, your data will be eliminated from the study.

There is no financial remuneration for participating in this study.

If you have any questions about any aspect of this study or your involvement, please contact

Carolyn Kenny, Ph.D.
Chair, Institutional Review Board
Antioch University
Ph.D. in Leadership and Change
Tel: 805-565-7535
email address: ckenny@phd.antioch.edu

Two copies of this informed consent form have been provided. Please sign both, indicating that you have read, understood and agreed to participate in this research. Return one to me and keep the other for yourself.

_____

Name of researcher (please print)

_____

Signature of researcher

_____

Date

_____

Name of participant (please print)

_____

Signature of participant

_____

Date

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